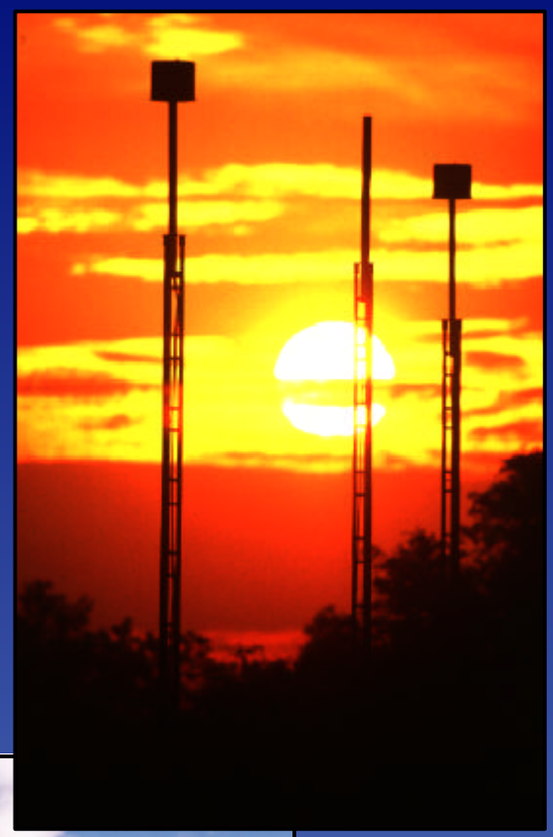
U.S. Environmental Protection Agency (EPA)

Clean Air Status and Trends Network (CASTNet)



Quality Assurance Project Plan

Appendix 9

Quality Management Plan

Prepared by:

Harding ESE

A MACTEC COMPANY

May 2002

MACTEC, Inc.

QUALITY ASSURANCE MANUAL

MACTEC, Inc.:

Scott E. State, Chief Executive Officer — Date: 5/13/02

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Vickie Presnell, EPA Project Officer — Date: 5/28/02

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Effective Date: 5/28/02

QUALITY ASSURANCE MANUAL

POLICY VOLUME

Effective Date: April 8, 2002
Revision Date: N/A

MACTEC, Inc.

Approvals:			
Harley Kirschenmann /S/	03/12/02	Scott State /S/	03/12/02
Quality Assurance Manager	Date	Chairman & CEO	Date

POLICY VOLUME

Table of Contents

1.0 Quality Organization

The activities of the MACTEC, Inc. family of companies are performed in accordance with applicable federal and local laws. The policies and procedures of MACTEC, Inc. and its subsidiaries contained in this manual describe the quality function at each level of responsibility and authority.

The MACTEC, Inc. family of companies provides a wide variety of management consulting and technical support services to businesses, utilities, industries, and government. These services include activities such as:

- ✓ project and program management
- ✓ air resources
- ✓ industrial hygiene/occupational health
- ✓ data management
- ✓ environmental communications
- ✓ environmental engineering
- ✓ telecommunications services
- ✓ engineered construction
- ✓ facilities engineering
- ✓ geosciences
- ✓ construction/construction management
- ✓ remediation/restoration
- ✓ value engineering/analysis services
- ✓ pollution prevention
- ✓ environmental assessments, management, and compliance
- ✓ strategic environmental management services
- ✓ risk assessment and ecology
- ✓ transportation services
- ✓ water resources
- ✓ industrial risk services

Regardless of the specific activities provided, MACTEC, Inc. is committed to providing the best managerial, technical, and professional services possible. Our goal is to help clients successfully manage complex businesses, projects, and facilities.

Local office managers shall document organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality.

The organization chart (Figure 1) depicts the relationships of organizational units within MACTEC, Inc. The organization is designed as a matrix of functions and support capabilities, to best serve customers as well as the company.

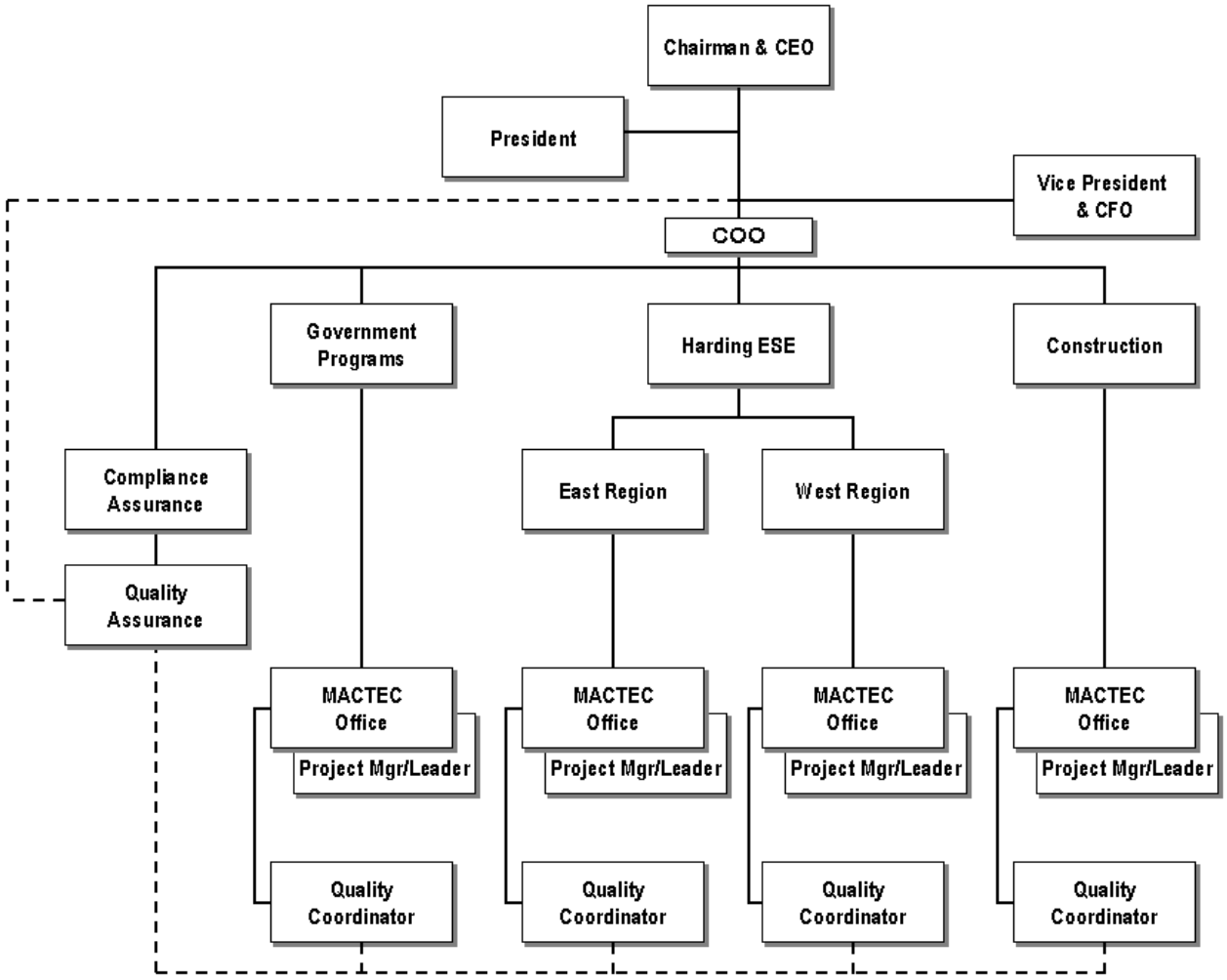


Figure 1. MACTEC, Inc. Organization

❖ *See Procedure Volume Section 1-1, Organization*

2.0 Quality Assurance Program

The Chairman and Chief Executive Officer (CEO) of MACTEC, Inc. is responsible for an effective, efficient Quality Program. The function of this program is to provide sufficient controls so that products and services meet clients' requirements and needs and exceed their expectations.

The Chairman and CEO of MACTEC, Inc. delegates responsibility for development and implementation of the corporate Quality Assurance Program to MACTEC, Inc.'s Corporate Quality Assurance (QA) Manager.

Each local office shall comply with the requirements of this corporate Quality Assurance Manual.

The detection and prevention of problems to quality is key to the management philosophy of MACTEC, Inc. Quality improvement in MACTEC, Inc. activities and throughout the family of companies as well as with partners is fundamental to our success and continued business. Identified quality issues and concerns are considered opportunities for improvement.

Every individual within MACTEC, Inc. and its subsidiaries is responsible for implementing the Quality Assurance Program under the explicit authority of the Chairman and CEO. They have access to work areas, personnel, and documentation required to carry out their duties.

❖ *See Procedure Volume Section 2-1, Quality Assurance Program*

Qualification and Certification of Personnel

Quality Assurance Programs and Quality Project Plans shall provide for the indoctrination and training, as necessary, of personnel performing activities affecting quality and for verification in accordance with this manual and/or contractual requirements. Training is conducted by qualified personnel and documented when required.

The employees of MACTEC, Inc. and its subsidiaries are encouraged to learn new skills and techniques that help them better perform their work activities.

❖ *See Procedure Volume Section 2-2, Qualification and Certification*

Work Control

Project work activities shall be controlled to ensure that they comply with the applicable requirements of this Quality Assurance Manual and/or contractual requirements.

❖ *See Procedure Volume Section 2-3, Work Control*

Quality Assurance Project Plans

MACTEC, Inc. Division Management shall ensure that local offices develop Quality Project Plans (QPP's), when appropriate, for MACTEC, Inc. projects. A

Quality Project Plan shall describe the quality assurance and quality control activities that must be performed to ensure the results of contractual and quality requirements established by MACTEC, Inc. and a client.

❖ *See Procedure Volume Section 2-4, Quality Assurance Project Plans*

3.0 Design Control

Local office Project Managers and QA Coordinators shall maintain design control including provisions for specifying and meeting quality standards related to design control in accordance with the requirements of this manual and the requirements of the current MACTEC, Inc. Design Process Manual.

❖ *See Procedure Volume Section 3-1, Design Control*

4.0 Procurement Document Control

MACTEC, Inc. and its subsidiaries shall ensure that purchasing documents are controlled to meet regulatory and client contractual requirements in accordance with this manual and the current MACTEC, Inc. Procurement Manual.

❖ *See Procedure Volume Section 4-1, Procurement Document Control*

5.0 Instructions, Procedures, and Drawings

Quality-related work activities shall be performed in accordance with instructions, procedures, and drawings that ensure activities are properly performed and that project-specific and contractual requirements are met. These work control documents shall include appropriate qualitative and quantitative acceptance criteria for determining the activities have been satisfactorily accomplished.

❖ *See Procedure Volume Section 5-1, Instructions, Procedures, and Drawings*

6.0 Document Control

Local office Project Managers and/or QA Coordinators shall ensure that the preparation, issue, and changes to documents specifying quality requirements or prescribing activities affecting quality are controlled.

❖ *See Procedure Volume Section 6-1, Document Control*

7.0 Control of Purchased Items and Services

Control of purchased items and services shall provide, as appropriate, for the following: source evaluation and selection, evaluation of objective evidence of quality furnished by a supplier, source inspection, audit, and examination of items, data, and/or services upon completion or delivery.

- *See Procedure Volume Section 7-1, Control of Purchased Items and Services*

8.0 Identification and Control of Materials, Parts, and Components

Controls shall be established to ensure that correct and accepted items are used and/or installed. Identification of these items shall be maintained on the items or in documents traceable to the items, or in a manner that ensures that identification is established and maintained.

- *See Procedure Volume Section 8-1, Identification and Control of Materials, Parts, and Components*

9.0 Control of Special Processes

Special quality processes, such as those used in work involving the environment, welding, heat treating, and nondestructive examination, of items, data, and services shall be controlled and performed by qualified personnel using qualified procedures or work documents in accordance with MACTEC, Inc. and/or client quality requirements, as appropriate.

- *See Procedure Volume Section 9-1, Control of Special Processes*

10.0 Inspection, Examination, Surveillance, and Testing

Inspections required to verify conformance of an item, activity, or computer program to specified requirements shall be planned and executed, the results of which shall be documented. The characteristics of the items or activities to be inspected and the method of inspection shall be specified. Inspections for acceptance of items and activities shall be performed by individuals other than those who performed or directly supervised the work being inspected.

- *See Procedure Volume Section 10-1, Inspection, Examination, Surveillance, and Testing*

11.0 Test Control

Tests which are required in order to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed, the results of which shall be documented. Appropriate acceptance criteria shall be based upon the characteristics to be tested. Test methods shall be specified and conformance with acceptance criteria shall be evaluated. Where collection of data, such as for siting or design input, is required, tests shall be planned, executed, documented, and evaluated.

- *See Procedure Volume Section 11-1, Test Control*

12.0 Control of Measuring and Test Equipment

Measuring and test equipment, such as tools, gauges, instruments, and any other test and/or measuring equipment used for quality-related activities, shall be controlled, calibrated, and adjusted at specified intervals to maintain accuracy within necessary limits.

- *See Procedure Volume Section 12-1, Control of Measuring and Test Equipment*

13.0 Handling, Storage, and Shipping

In order to prevent damage or loss to items, and to minimize deterioration, if appropriate, the handling, storage, cleaning, packaging, and shipping of items shall be controlled and conducted in accordance with established work and inspection requirements.

- *See Procedure Volume Section 13-1, Handling, Storage, and Shipping*

14.0 Inspection, Test, and Operating Status

Project Managers shall ensure the use of status indicators is defined in work documents to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Work documents shall specify requirements for status indicators. Cognizant inspection personnel shall identify inspection and test status on the items or in documents traceable to the item or activity.

- *See Procedure Volume Section 14-1, Inspection, Test, and Operating Status*

15.0 Nonconforming Materials, Parts, or Components

The MACTEC, Inc. nonconformance control process captures known and perceived deficiencies, defects, and failures to comply.

Controls shall be provided for materials, part, components, and other items that do not conform to specified requirements to prevent installation or use of those items. The controls shall provide for identification of the items, documentation, evaluation, segregation when practical, and disposition of nonconforming items. Affected organizations shall be informed of nonconforming items.

- *See Procedure Volume Section 15-1, Nonconforming Materials, Parts, or Components*

16.0 Corrective Action

The corrective action management process provides for correction and prevention of problems and their recurrence.

Conditions adverse to quality shall be identified and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action is required to verify implementation of the corrective action.

For nuclear related projects, the requirements of Federal Regulation 10CFR21, Section 206 shall apply for potentially reportable incidences.

- *See Procedure Volume Sections 16-1, Corrective Action; and Nuclear – Related Procedure 1, Reporting Nuclear-Related Deficiencies, Defects, or Noncompliances – Federal Regulation 10CFR21, Section 206*

17.0 Quality Records

Records generated as a result of quality-related activities shall be maintained, legible, identifiable, and retrievable. Requirements shall be established and documented for transmittal, distribution, retention, maintenance, and disposition. Records shall be protected against damage, deterioration, and loss.

- *See Procedure Volume Section 17-1, Quality Assurance Records*

18.0 Audits

The MACTEC, Inc. audit and assessment processes are designed to detect, correct, and prevent problems adverse to quality.

Audits shall be planned, scheduled, implemented, and performed to verify compliance with MACTEC, Inc. and client contractual quality requirements. The results of audits shall be used to determine the effectiveness of the quality management program and project-specific quality plans. Audits shall be performed in accordance with written procedures or checklists and by qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented in audit reports and reported to and reviewed by responsible management. Follow-up action shall be taken when appropriate.

- *See Procedure Volume Section 18-1, Audits*

QUALITY ASSURANCE MANUAL

PROCEDURE VOLUME

Effective Date: April 8, 2002
Revision Date: N/A

MACTEC, Inc.

Approvals:			
Harley Kirschenmann /S/	*03/12/02*	*Scott State /S/*	*03/12/02*
Quality Assurance Manager	*Date*	*Chairman & CEO*	*Date*

Table of Contents

Procedure Title: ORGANIZATION

1.0 PURPOSE

This procedure describes MACTEC, Inc.'s organization and interrelationships in the performance of activities affecting quality.

2.0 SCOPE

The quality requirements contained in this section apply to MACTEC, Inc. and its subsidiaries.

3.0 GENERAL

3.1.1 MACTEC, Inc. provides a wide variety of management consulting and technical support services to businesses, utilities, industries, and government. These services are dependent on the contract involved, but generally relate to: management consulting; project and program management; environment, safety and health management; quality management; information technology; training; plant operations; regulatory and litigation support; maintenance management; design/engineering and engineering management; and construction/construction management.

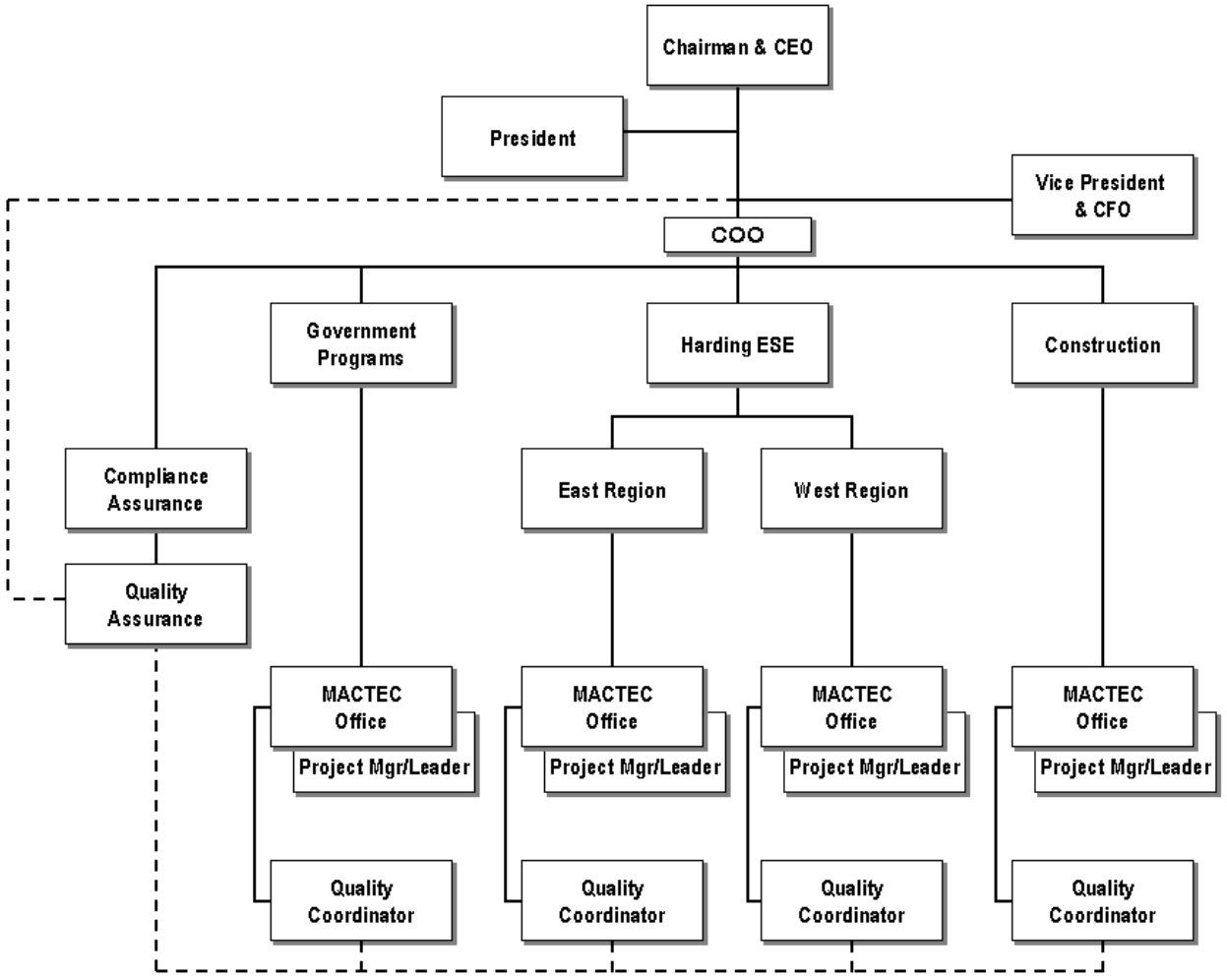
3.1.2 Regardless of the specific activities provided, MACTEC, Inc. is committed to providing the best management, technical, and professional services possible to help clients successfully manage complex businesses, projects, and facilities. Local offices and their Project Managers have responsibility for ensuring that MACTEC, Inc. products and services meet client requirements. To achieve this, effective and efficient management controls have been established to guide project performance; the controls are applied to each project as appropriate and in accordance with this Quality Assurance Manual.

3.2 ORGANIZATION

3.2.1 The organization chart (Figure 1) depicts the relationships of organizational units of MACTEC, Inc. covered by this Quality Assurance Manual. A "matrix type" organizational structure has been established in which projects are organized with management established in a functional organization and support provided as required from management and/or other organizations consistent with the scope of work performed.

3.2.2 Local offices and their managers document a project's organization, along with interfaces depicting client and MACTEC, Inc. organizational elements. The documentation includes the responsibility and authority of each organizational element. The documentation may be a part of a project plan and/or the Quality Project Plan.

Figure 1. MACTEC, Inc. Organization



(This organization chart depicts the typical representation of the MACTEC, Inc. organization for quality-related activities. The chart may not be current; current versions of the chart are available in the MACTEC, Inc. corporate office or current corporate website @www.mactec.com)

3.3 ORGANIZATION ROLES AND RESPONSIBILITIES

3.3.1 MACTEC, Inc. family of companies and employees are responsible for implementing the Quality Assurance Program under the explicit authority of the Chairman and CEO. They have access to work areas, personnel, and documentation required to carry out their duties. When performing a verification function under the Quality Assurance Program, personnel must maintain independence from direct performance of project work for those activities for which they perform verifications, including cost and schedule considerations.

3.3.2 Every employee has the authority to stop work that may result in an adverse impact on quality, the environment, health and safety, or compliance with contractual documents or legal requirements.

3.3.3 This document, the Quality Assurance Procedure Volume, assigns responsibilities for performing Quality Assurance Program activities. The quality of services provided is the responsibility of the local office management and the organizational units performing the work or affecting the services provided.

3.4 CHAIRMAN AND CHIEF EXECUTIVE OFFICER (CEO)

3.4.1 The Chairman and Chief Executive Officer (CEO) of MACTEC, Inc. is responsible for an effective, efficient Quality Assurance Program. The function of this program is to provide sufficient controls so that products and services meet clients' requirements and needs, and exceed their expectations. The Chairman and CEO approves the MACTEC, Inc. Quality Assurance Program and the Quality Assurance Manual.

3.5 CHIEF OPERATING OFFICER (COO)

3.5.1 The Chief Operating Officer is responsible for the business operations of MACTEC, Inc.'s three operating divisions. The COO is responsible for ensuring MACTEC, Inc's Quality Assurance Program and Quality Assurance Manual is implemented throughout the three operating divisions.

3.6 PRESIDENT

3.6.1 The office of the President focuses on achieving operational excellence throughout MACTEC, Inc., facilitating synergy between each of the business units and maximizing the efficiency of corporate support functions. To facilitate achieving these objectives, the Human Resources, Management Information Systems (MIS), Risk/Litigation Management, Corporate Communications and Marketing Support, and Facilities functions report directly to the President.

3.7 VICE PRESIDENT AND CHIEF FINANCIAL OFFICER

3.7.1 The office of the CFO is responsible for overseeing MACTEC, Inc.'s financial activities which include budgeting, financial planning, general accounting and project planning and

control, purchasing, contract pricing and negotiations, subcontract administration, tax planning, cash management and coordination of audits.

3.8 CORPORATE QUALITY MANAGER

3.8.1 The Corporate Quality Manager is responsible for developing the Quality Assurance Program and promoting its implementation. The Quality Manager develops, approves, and maintains this Quality Assurance Manual, including changes thereto.

3.8.2 The Quality Manager is responsible for ensuring that a system is established to identify and address project deficiencies by appropriate project or corporate management and that further activities are controlled until the quality concerns are resolved.

3.8.3 Should a situation arise where the Quality Manager is involved in or responsible for activities related to identified quality concerns, the Quality Manager will identify a project quality leader. In this capacity, the project quality leader reports directly to the Chairman and CEO and investigates the identified concern through resolution.

3.8.4 The Quality Manager is responsible for establishing a process for the conduct of periodic audits to assure compliance with the requirements of the Quality Assurance Manual and to assess its effectiveness.

3.9 PROJECT MANAGERS

3.9.1 Project Managers have overall responsibility for delivering project quality results when clients contract for MACTEC, Inc. services to be performed in accordance with this MACTEC, Inc. Quality Assurance Manual.

3.9.2 Project Managers have responsibility for ensuring that MACTEC, Inc. products and services meet client requirements. To achieve this, effective and efficient management controls, such as the controls in this Quality Assurance Manual, the Design Process Manual, and the Procurement Manual, have been established to guide project performance. The controls are applied appropriately to each project. Project Managers ensure the following:

A. A project Quality Project Plan is developed when needed and as appropriate to meet the requirements of contractual documents.

B. Performance of direct QA functions for the client complies with the requirements of applicable regulations, codes, and standards.

C. Qualified individuals who have been indoctrinated in contract requirements and the client's QA program perform project work.

D. The quality of direct work performed by MACTEC personnel satisfies MACTEC QA standards of excellence.

E. Verification of the quality of such work is accomplished, reports are documented, and records maintained in accordance with client requirements.

F. Stop work orders are given in order to prevent further performance of work of unacceptable quality.

G. Quality concerns are addressed.

3.9.3 Should a Project Manager fail to adequately address an identified quality-related concern, other project personnel should submit their concern to the next appropriate level of management, including the corporate Quality Manager and/or Chairman and CEO, as the ultimate resolution authorities.

3.10 QA COORDINATORS

3.10.1 A Coordinators are identified for each MACTEC, Inc. office to support the development, implementation, and assessment of projects.

3.10.2 QA Coordinators report to the MACTEC, Inc. Office Manager and are responsible to Project Managers for project quality activities, as applicable.

3.10.3 QA Coordinators direct the quality efforts on a project and fulfill project quality requirements when needed. Specific responsibilities of a Quality Coordinator typically include:

A. Identifies quality-related matters.

B. Evaluates stop work requests for appropriate action to prevent further performance of work of unacceptable quality.

C. Serves as the communications contact between the client and MACTEC, Inc. for quality-related matters.

D. Assures the identification and documentation of appropriate quality-related requirements pertaining to the client's activities for which MACTEC, Inc. services have been contracted, including any requirements exceeding currently accepted practices.

E. Assists the Project Manager in assigning qualified MACTEC, Inc. personnel to specific tasks.

F. Determines the need for and provides required job instruction, indoctrination, training, and clearances.

G. Determines the need for checklists, plans, guides, procedures, or other documents and, when required, evaluates their adequacy.

H. Provides review of work performed by MACTEC, Inc. personnel to assure acceptability and conformance to contractual obligations.

I. Verifies the completion of work in accordance with MACTEC, Inc.'s contractual requirements.

3.11 PROJECT TEAM MEMBERS AND STAFF PERSONNEL

3.11.1 Project team members and staff personnel have the responsibility to achieve quality results for their projects, products, and services.

3.11.2 Project personnel have the authority to identify quality concerns and to initiate a stop work request to the Quality Coordinator and/or appropriate management personnel; project personnel may recommend or provide solutions to those quality concerns.

3.12 OFFICE MANAGERS

3.12.1 Office Managers are established for each MACTEC, Inc. office. The Office Managers have administrative responsibility for the successful functional operations of their organizations that include, but are not limited to, human resources, sales and marketing, procurement, quality, and engineering organizations.

3.12.2 Individual local offices and project organizations identify and implement quality requirements appropriate for the activities for which they have responsibility. Verifying achievement of quality is assigned to personnel other than those involved in performing or supervising the work being verified. Any or all of this work may be delegated in writing to others; however, the responsibilities shall remain as noted above.

3.13 IDENTIFYING QUALITY ISSUES AND RESOLVING DIFFERENCES OF OPINIONS

3.13.1 The Project Manager, the corporate QA Manager and the QA Coordinators have the authority and responsibility to identify quality problems related to work for which MACTEC, Inc. is responsible and to correct problems, including when necessary, the authority to stop work in order to prevent further performance of work of unacceptable quality.

3.13.2 Resolution of differences of opinion between QA personnel and other department or organization personnel shall be accomplished through discussion and mutual agreement between participants. If mutual agreement cannot be reached, the dispute shall be resolved at the next appropriate level of management. The ultimate responsibility for

resolution shall rest with the Corporate Quality Manager and/or the Chairman and CEO of MACTEC, Inc.

4.0 RECORDS

There are no records generated by the requirements of this section of the manual.

- *See Policy Volume 1.0, Organization*

Procedure Title: QUALITY ASSURANCE PROGRAM

1.0 PURPOSE

This section establishes the method of implementing appropriate Quality Assurance (QA) Program requirements for each project so that client requirements are met and project objectives are accomplished in an efficient and cost-effective manner with quality results.

2.0 SCOPE

The quality requirements of this section apply to MACTEC, Inc. and its subsidiaries.

3.0 GENERAL

An effective and complete QA Program is planned, documented, implemented, and maintained to provide organizational and functional disciplines and requirements necessary to control and furnish adequate product and service quality and objective evidence of quality activities throughout all phases of contract performance.

3.1 PROGRAM APPLICABILITY

3.1.1 The application of the QA Program is at the individual client project level. The program is applied to all MACTEC, Inc. project products and services using a graded approach, in accordance with the applicable contractual requirements, and at the earliest time consistent with the project schedule. The establishment of the program considers the technical aspects of the activities affecting quality.

3.2 QA PROGRAM BASIS AND IMPLEMENTATION

3.2.1 The MACTEC, Inc. corporate QA Program has been developed to provide flexibility to meet the various QA related regulations and standards required of clients. The use of a Quality Project Plan will be the vehicle to address client specific regulations/standards and associated requirements that are not addressed by this manual. The Quality Project Plan identifies project-specific supplementary manuals, procedures, and instructions to implement quality requirements/standards not addressed in this manual.

3.2.2 This MACTEC, Inc. QA Manual has a policy volume and procedure volume organized to correspond to the criteria of several regulations, codes, and standards. The sections of the procedure manual define the discrete elements/processes that comprise the overall MACTEC, Inc., QA management program.

3.2.3 MACTEC, Inc. work activities will comply fully with applicable regulations, codes and standards to which the work is subject. MACTEC, Inc. will not knowingly accept direction that would result in violation of any legal requirement.

3.3 QA PROGRAM IMPLEMENTATION

3.3.1 Prior to initiating work for a client, the proposed contract shall be reviewed to ensure that requirements are clearly defined and understood, any differences between the client's request for proposal and the actual contract are resolved, and MACTEC, Inc. has, or can readily acquire, the capability to meet requirements. Records of such review are maintained as a nonpermanent quality record.

3.3.2 When required by the client contract or because of the complexity of the activities involved in a project, the Project Manager will develop a Quality Project Plan in accordance with section 2-4 of this manual. The Quality Project Plan will define the application of the MACTEC, Inc. QA Program to the specific project products and services. Quality Project Plans are developed for all projects that involve:

A. Implementation of a client's QA program's standards/requirements.

B. Implementation of a combination of the requirements of this MACTEC, Inc. QA manual and a client's QA program.

C. Collection and/or analysis of environmental data.

D. MACTEC, Inc. providing design services.

E. A client required formal quality improvement plan for a project.

3.3.3 Quality-related activities are conducted and controlled using documented procedures appropriate to the complexity and rigor of the work (this includes instructions, drawings, process diagrams, data collection, or other appropriate documents). These procedures may be the procedures within this QA Manual or other MACTEC, Inc. manuals; procedures provided by the client; or procedures developed by MACTEC, Inc. or others for the specific contract.

A. The procedures used shall specify quality-related activities performed and accomplished under suitably controlled conditions. Examples of suitably controlled conditions include use of appropriate equipment, any environmental restriction, and verification that necessary prerequisites for the MACTEC, Inc. activities have been met.

B. The procedures will identify activity/task-specific training required; special processes and controls; test equipment or tools needed; and any special skills required.

3.3.4 MACTEC, Inc. provides qualified personnel in various special areas to help clients meet their work requirements. MACTEC, Inc. also may provide a full staff to conduct all or part of a client's project for a specified period, acting as the client's agent. Each client employing MACTEC, Inc. services, in either of those direct capacities, has the option of having the work accomplished in accordance with the client's own QA program requirements and procedures, or having the work performed in accordance with a specific Quality Project Plan for the contract. The Quality Project Plan addresses how work is performed in accordance with this QA Manual, or a modified program tailoring applicable sections of this QA Manual and other documents to the specific client situation.

3.4 GRADED APPLICATION

3.4.1 The approach to a graded application of the MACTEC QA Program is typically documented in a project-specific Quality Project Plan (QPP). Applicable project procedures and/or work documents implement the project-specific grading.

3.4.2 Risk is the fundamental consideration in determining to what extent the requirements of this manual apply. Certain activities, items, or processes may require extensive control measures while others may require only a limited degree of control. The control measures that are to be considered include procedural coverage, qualification and training, peer reviews, surveillances, audits, and assessments. The application of and degree to which these control measures are employed for an activity, item, or process is established through the risk analysis/assessment process.

3.4.3 The risk analysis/assessment process shall meet client requirements and take into account such factors as:

A. Relative importance to safety, safeguards, and security.
B. Magnitude of any hazard involved.
C. Life cycle stage of the facility.
D. Programmatic mission.
E. Particular characteristics of the facility.
F. Consequences of failure.
G. Probability of failure.
H. Complexity or uniqueness of design or fabrication techniques.
I. Special controls.
J. Ability to demonstrate functional compliance.
K. Quality or safety history.
L. Impact on the environment.

M. Impact on cost an/or schedule.

3.5 ISSUANCE AND CONTROL OF THE QUALITY ASSURANCE MANUAL

3.5.1 The corporate QA Manager, or designee, is responsible for the preparation, control and revision, and distribution of the QA Manual.

3.5.2 Each QA Manual section contains a revision number and the date of issuance and is approved and signed by the MACTEC, Inc. Chairman and CEO and corporate QA Manager.

3.5.3 The Corporate Development Office shall be responsible for distribution of QA Manuals and section revisions to locations when required. The QA Manual also is available electronically via the MACTEC, Inc. corporate website.

3.5.4 When a QA Manual section is revised, that section is reissued in its entirety with each page indicating the new revision number and is accompanied by a change in the Table of Contents. Revisions are reviewed and approved in the same manner as the original sections.

3.5.5 When a client needs to meet specific industry requirements, this QA Manual may be modified. Site- specific changes or the generation of a project-specific manual will have the same approval cycle as this QA Manual.

3.5.6 Quality Project Plans and supplementary procedures or QA Manual sections may be generated when required by the client. Client contract documents of a particular project are identified in the specific Quality Project Plan, and apply only to the project for which they are prepared. Special procedures may be implemented in lieu of MACTEC, Inc.'s QA Manual section for a specific project, when necessary, for the type or scope of the project or service provided. These revisions do not affect the corporate issue QA Manual, other project-specific procedures, or project-specific QA manuals unless deemed necessary by the corporate QA Manager.

3.6 TRAINING

3.6.1 MACTEC, Inc. personnel performing activities affecting quality receive training/indoctrination to ensure that they are knowledgeable of the applicability, purpose, scope and implementation of this QA Manual as applied to the project; any Quality Project Plan; client-specific quality program requirements; applicable regulatory requirements; project-specific instructions and procedures; and their job responsibilities and authority. Such indoctrination may be by formal classes, through completion of a required reading list, or by briefings. Training is provided as needed to achieve initial proficiency, maintain proficiency, and adapt to changes in project requirements, technology, methods, or job responsibility. Formal training, when applicable, includes

instruction in principles and techniques of the activity being performed to the extent necessary to assure competence in the activity. Indoctrination and training is documented in accordance with Section 2-4 of this procedure volume. Functional area activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, constructing, installing, inspecting, testing, operating, maintaining, repairing, modifying, data collection, and decommissioning.

3.6.2 The corporate QA Manager, or designee, is responsible for indoctrinating appropriate MACTEC, Inc. management and supervisory personnel in the basis for, objectives of, and methods for assuring quality of MACTEC, Inc. work and for determining the appropriate method of indoctrinating and training company personnel.

3.6.3 For activities requiring certification and qualification, such as audit and inspection personnel, training is accomplished and documented prior to performing those activities.

3.6.4 The extent of indoctrination and training is determined by the QA Coordinator and is commensurate with the following:

A. The scope, complexity, and nature of the activity.

B. The education, experience, and proficiency of the trainee.

3.6.5 Ongoing training is conducted in a timely manner when applicable procedures, program manuals, regulations, codes, or standards requirements are added or revised, in order to ensure that personnel are maintaining the ability to perform their assigned duties and responsibilities satisfactorily.

3.6.6 On-the-job training is conducted for those circumstances where the complexity, nature, or extent of an activity requires hands-on training in order for personnel to understand and perform their assigned duties and responsibilities.

3.6.7 The training of personnel is structured to provide a necessary background in QA, and instructions/procedures appropriate for the performance of activities affecting quality; this training is documented.

3.6.8 Records of the implementation of indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

3.7 QUALITY IMPROVEMENT

3.7.1 It is a basic concept of quality improvement that all work activities can be planned, performed, measured, and improved. Managers at all levels are responsible for creating an atmosphere where improvement is continuous and an integral part of the work activities. In achieving that, managers should encourage the development and

exploration of new ideas. Managers are expected to increase staff awareness of the importance of quality and emphasize enhanced product and process safety and reliability, including the identification of nonconforming items and potential areas for improvement.

3.7.2 The MACTEC, Inc. QA program requirements include methods to detect and prevent quality problems and to ensure quality improvement.

3.7.3 MACTEC, Inc. products, services, and processes that do not meet established requirements are identified, and controlled in accordance with this procedure and Section 15, Nonconformances; they are corrected through the Corrective Action Process documented in Section 16. The process of correction includes identifying the causes of problems and preventing recurrence.

3.7.4 Quality Managers/Quality Coordinators shall establish procedures to periodically perform a trend analysis of nonconformances and corrective actions when required by contractual agreements.

3.7.5 The combination of internal MACTEC, Inc. audits and management reviews serve as tools for identifying opportunities for improvement.

3.7.6 Work process performance should be measured and evaluated continually to identify improvement opportunities. Because of the diverse nature of the products and services provided to clients by MACTEC, Inc., additional project-specific reviews may be necessary.

3.7.8 Each Project Manager is responsible for managing process quality for projects and identifying potential improvements to the cognizant QA Coordinator, QA Manager, the Chairman and CEO, or other corporate team member(s) responsible for the corporate definition of the processes involved. During training for project-specific work activities, the Project Manager and/or QA Coordinator shall emphasize the responsibility project team members have towards understanding how the processes contribute to the success of the overall project effort.

3.7.9 The quality improvement activities described in paragraph 3.7.1 are supplemented by quality improvement reviews by Project Managers and cognizant QA Coordinators. The frequency of the reviews are documented in a project plan and/or the Quality Project Plan. The frequency of quality improvement reviews should be determined in consideration of the number of MACTEC, Inc. personnel assigned to the project, the duration of the project, and the scope and complexity project activities.

3.7.10 When client contracts specify the establishment of a quality improvement process, the contractual requirements are implemented through the Quality Project Plan.

3.8 ANNUAL MANAGEMENT REVIEW

3.8.1 The management of local office organizations and the corporate office implementing the QA Program, or portions thereof, ensure performance of, as a minimum, an annual review that assesses the effectiveness of the QA Program to assure that the program is meaningful; effectively complies with applicable codes, standards and regulatory guides; and effectively implements the elements, as stated in this QA Manual. Records of such review(s) are maintained in accordance with Section 17-1 of this manual, Quality Assurance Records (See Appendix 17.1.1, Typical Example of Records Disposition and Retention Schedule).

4.0 RECORDS

Records generated by the requirements of this section are maintained in accordance with Section 17-1, Quality Assurance Records.

- *See Policy Volume 2.0, Quality Assurance Program*

Procedure Title: QUALIFICATION AND CERTIFICATION OF PERSONNEL

1.0 PURPOSE

This section establishes requirements and describes the process for developing, implementing, and maintaining programs for the indoctrination and training of personnel to ensure a competent work force in performing activities affecting the quality of MACTEC, Inc. services.

2.0 SCOPE

The quality requirements of this section apply to QA personnel of MACTEC, Inc. and its subsidiaries when assigned to tasks associated with commercial best practices and the requirements associated with industry standards, such as ASME and ANSI.

3.0 GENERAL

3.1 QUALITY ASSURANCE PROGRAM FAMILIARIZATION

MACTEC, Inc. typically employs personnel who are thoroughly trained and experienced in each technical field and who need only to be familiarized with the MACTEC, Inc. QA Program requirements, or the appropriate procedures controlling the activities and the equipment, methods, and practices used to be able to perform their assigned tasks.

3.2 QUALITY ASSURANCE PROGRAM INDOCTRINATION

The corporate QA Manager, or designee, is responsible for ensuring that personnel performing quality-related activities in accordance with this QA Manual and applicable requirements of each particular project are adequately trained in those QA procedures associated with their work assignment. Project Managers and QA Coordinators are responsible for determining whether client- approved procedures or those of this manual are applicable. Where client procedures apply, MACTEC, Inc. personnel receive appropriate indoctrination and training in such requirements. Indoctrination includes the technical objectives and requirements of the applicable codes and standards, and the QA program elements that are to be employed. Documentation of the QA Program indoctrination is retained in the appropriate MACTEC, Inc. personnel/qualification file. The QA Manager, or designee, and QA Coordinator(s) periodically assess MACTEC, Inc. activities to assure compliance with this manual.

3.3 NEW HIRES

MACTEC, Inc. Human Resources uses a third party background investigations company to obtain verifications on, but not limited to, education and experience in order to comply with client requirements. Verification addresses the minimum that is required by the applicable position description and any specific requirements imposed by a client

contract or purchase order. The Recruiting Department within Human Resources conducts reference checks on all employees. The MACTEC, Inc. appointed Project Manager is responsible for notifying Human Resources of such client requirements and for verifying that the requirements have been met.

4.0 IMPLEMENTATION

4.1 INSPECTION, EXAMINATION, AND TESTING PERSONNEL

4.1.1 QA Coordinators designate those activities that require qualified inspection, examination and test personnel, and the minimum requirements for such personnel.

4.1.2 Personnel selected for performing inspection, examination and test activities shall have experience and training commensurate with the scope, complexity, or special nature of the activities. Only those personnel who meet the requirements of this section are permitted to perform inspection, examination and test activities.

4.1.3 The requirements identified by this section define the capabilities that qualify personnel to perform inspections, examinations, and tests. There are three levels of qualification: Levels I, II and III (see Appendix 2.2.1, Qualification Logic Chart). The requirements are not limiting with regard to organizational position or professional status, but are limiting with regard to discipline or functions performed within the disciplines. Examples of major MACTEC, Inc. disciplines are shown below:

A. Mechanical/Welding
B. Electrical
C. Instrumentation and Controls
D. Receipt
E. Civil and Structural
F. Test and Measurement

4.1.4 Level I personnel shall have experience or training in the performance of inspections or testing they will be required to perform. Capabilities shall include:

A. Familiarity with and demonstrated proficiency in the use of applicable tools and equipment.

B. Capability of determining calibration status of inspection and measuring equipment and capability that the measuring and test equipment is in proper condition for use.

C. Capability of determining if inspection, examination, and test procedures are approved for use.

D. Capability of performing the inspection, examination, and test that are required to be performed in accordance with documented procedures and/or industry practices.

4.1.5 Level II personnel shall have all of the capabilities of Level I personnel for the inspection, examination, or test category or class in question. In addition, capabilities shall include:

A. Planning inspections, examinations, and tests.

B. Setting up tests, including preparation and set-up of related equipment, as appropriate.

C. Supervising or maintaining surveillance over the inspections, examinations, and tests.

D. Reporting inspection, examination, and test results.

E. Evaluating the validity and acceptability of inspection, examination, and test results.

F. Certifying lower level personnel.

4.1.6 Level III personnel shall have all of the capabilities of Level II personnel for the inspection, examination, or test category or class in question. In addition, the individuals shall also be capable of evaluating the adequacy of specific programs used to train and certify test inspection, examination, and test personnel.

4.1.7 Minimum required capability levels are as follows:

	Level		
Project Function	**L-I**	**L-II**	**L-III**
Recording inspection, examination, and testing data	X	X	X
Implementing inspection, examination, and testing procedures	X	X	X
Planning inspections, evaluations, and tests; setting up tests including preparation and set-up of related equipment		X	X
Evaluating the validity and acceptability of inspection, examination, and testing results		X	X
Reporting inspection, examination, and testing results		X	X
Supervising equivalent or lower level personnel		X	X
Qualifying lower level personnel		X	X
Evaluating the adequacy of specific programs used to train and certify test inspection, examination, and testing personnel			X
Qualifying same level personnel			X

4.1.8 Where the performance of an activity requires special physical characteristics, including initial and subsequent physical examination, requirements shall be identified, implemented, and documented.

4.1.9 When vision examinations are required for inspectors in the performance of inspections, examination or acceptance testing, they are documented, as typically shown in Appendix 2.2.3, or by similar vision examination forms produced by a physician or a cognizant testing facility. Vision examinations may be performed using the following methods:

A. Visual Acuity: Natural or corrected near-distance acuity such that the individual is capable of reading J-1 letters on a standard Jaeger's test type chart, or of passing an equivalent test (where visual acuity is a factor in the required inspection, examination, or testing).

B. Color Vision: Perform satisfactorily on any recognized color vision test (where color perception is a factor in the required inspection, examination, or testing).

4.1.10 Upon successful verification of requirements for education, experience, training, and examinations as required, including visual examination, the authorized Level II or Level III individual signs and dates the "Personnel Qualification" Form (Appendix 2.2.2).

4.1.11 Specialists who perform inspections, surveillances, or examinations may require qualification and certification in accordance with the requirements of Section XI of the ASME Code for VT-2 and VT-3, or NQA-1, or as required by the client contract. Specialists who perform VT-1 examinations as defined in ASME Code, Section XI, are certified in accordance with ASNT-TC-1A. Qualification is documented using Appendix 2.2.2; certification is documented using Appendix 2.2.4.

4.1.12 NDE technicians who perform nondestructive examinations may require qualification and certification in accordance with established written procedures that fulfill the requirements of American Society for Nondestructive Testing recommended practice No. ASNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing." and Section XI of the ASME Code. Qualification is documented using Appendix 2.2.2; certification is documented using 2.2.4. Annual evaluation of each certified Level I, II, and III NDE is conducted and documented using Appendix 2.2.5.

4.1.13 Technical specialists and engineers who perform technical examinations and tests may require qualification and certification in accordance with ASME NQA-1, or as required by the client contract. Appendices 2.2.2 and 2.2.4 may be used to document qualification and certification.

4.1.14 MACTEC, Inc. often engages in work with clients in which subcontractors are used. Under these circumstances, MACTEC, Inc. may elect to certify subcontractor personnel to ensure their appropriate qualifications.

4.1.15 Personnel previously certified by organizations other than MACTEC, Inc. may be certified to their former level of certification by the corporate QA Manager, or designee, provided verification of certification can be obtained, the certification provided has been evaluated and found to be consistent with this program, and the following requirements have been verified:

A. Previous certification in the discipline.

B. Evidence that the individual has been working in the capacity to which he or she has been certified within six months of termination.

C. The individual has a current vision examination in accordance with the requirements of this program.

4.1.16 In addition to the education and experience documented in Appendix 2.2.2, MACTEC, Inc. "Personnel Qualification" Form, the form also indicates the discipline an individual is qualified to perform.

4.2 INITIAL CERTIFICATION AND RECERTIFICATION

Initial Certification: The designated Level II or Level III personnel evaluates (see paragraph 4.1.10) the candidate on the basis of the applicable MACTEC, Inc. "Qualification Logic Chart" (Appendix 2.2.1). Upon determination of the candidate's capability level, the evaluator shall complete and sign the "Personnel Qualification" Form (Appendix 2.2.2). The approved certificate is retained as a quality record (see paragraph 5.0).

Recertification is as follows:

A. Designated Level II or Level III personnel, as appropriate, re-evaluate the job performance of inspection, examination, and testing personnel at intervals not to exceed three years. Re-evaluation is evidenced of continued satisfactory performance or re-determination of capability. If, during this evaluation or at any other time, it is determined that the capabilities of an individual are not in accordance with the qualifications specified for the job, that person shall be removed from the activity until such time as the required capability has been demonstrated.

B. Individuals who have not performed inspection, examination, or testing activities in their qualified area for a period of one year shall be re-evaluated by a re-determination of required capability.

C. Recertification is documented on the "Personnel Qualification" Form (Appendix 2.2.2).

D. Where visual acuity is a condition of qualification, acuity is retested annually, and the results are documented and then attached to the most recent certification (use Appendix 2.2.3).

E. Where physical and/or health requirements are relevant to the assigned work, an individual's condition is verified by annual examination. Results are placed on file as a quality record in the MACTEC, Inc. personnel/qualification files.

4.3. QUALIFICATION AND CERTIFICATION OF PERSONNEL PERFORMING ASSESSMENTS

4.3.1 Assessor Categories: The three categories of qualification are as follows:

A. Assessor

B. Technical Consultant, Technical Specialist and/or Management Member of Assessment Team

C. Lead Auditor

4.3.2 Personnel selected for QA assessing/auditing assignments must have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

4.3.3 QA Coordinators should assist individuals with obtaining the necessary training by coordinating assessment/auditing training efforts with the corporate Quality Manager, or designee.

4.3.4 Personnel selected and assigned to an assessment/audit must be independent of any direct responsibility for performance of the activities that they assess or audit. The assessment team lead must, prior to commencing the assessment, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed.

4.3.5 Qualification of Assessors: An individual who performs duties as an assessor (including technical specialists) but who is not a certified Lead Auditor must have completed training and orientation in one of the following modes:

A. Orientation to the general structure of QA programs, review of applicable regulatory requirements, industry standards, codes, QA Manual Section 18-1, and MACTEC, Inc.'s and/or the client's audit procedures and practices where applicable;

B. Successful completion of an approved formal course or workshop conducted by the corporate QA Manager, or designee, or a professional organization approved and qualified to conduct the course or workshop; or

C. On-the-job training as an assessor or under the supervision of a qualified assessment Team Lead; guidance and counseling on the applicable elements of the assessment program shall be provided, including planning, performing, reporting and follow-up action involved when conducting assessments.

4.3.6 Assessor training is documented and certified on the "Assessor/Auditor Qualification Record" Form (Appendix 2.2.6).

4.3.7 Assessor qualification is normally a one-time requirement. Qualification is maintained through continued work in the position, remaining current by attending required and continued training, and satisfactory performance of work.

4.3.8 An assessor may function as an assessment Team Lead provided the assessor has demonstrated a high level of assessment proficiency and acceptable oral and written communication skills during previous assessment experiences as determined by a Project Manager and/or QA Coordinator.

4.3.9 Qualification of Technical Consultants, Technical Specialists and/or Management Members of Assessment Team: Technical Consultants, Technical Specialist and/or Management Members of Assessment Teams who provide specific technical expertise and assistance to a Lead Assessor of an assessment activity shall receive training that is appropriate to the complexity, scope, and type of assistance to be provided; training may include applicable requirements stated in paragraph 4.3.3 above.

4.3.10 Technical Consultants, Technical Specialist and/or Management Members of Assessment Teams are not considered assessors or Lead Assessors.

4.3.11 Qualification and Certification of Lead Auditor: Lead Auditors are required for nuclear-related audits and are qualified as follows:

A. The candidate for Lead Auditor qualification shall score at least ten points under the examination scoring system. The evaluation of the candidate's numerical score shall be shown on the "Lead Auditor Qualification" Form (Appendix 2.2.7).

B. The candidate is evaluated for oral and written communication skills by the corporate QA Manager. Acceptable skill is indicated in the space provided in Appendix 2.2.7.

C. The corporate QA Manager, or designee, and local office QA Coordinator determine the type and amount of training required for qualification as Lead Auditor. A decision that formal course work is not required is documented in the block labeled AUDIT TRAINING COURSES on the "Lead Auditor Qualification" Form (Appendix 2.2.7); such a decision is signed by the corporate QA Manager.

D. Unless exempted by management action per 4.3.8(c), the candidate must successfully complete training in at least one of the following modes: a formal course or workshop conducted by a qualified and approved individual or organization; or on-the-job training under the supervision of a certified Lead Assessor. The training provided shall include the following:

- Knowledge and understanding of codes, standards, regulations, and regulatory guides, as applicable.

- General structure of QA programs as a whole and applicable QA elements.

- Techniques of examining, questioning, evaluating, and reporting; methods of identifying and following-up on corrective action items; and methods for closing out audit findings.

- Audit planning in the quality-related functions.

E. The prospective Lead Auditor must have participated in a minimum of five QA audits within a period of time not to exceed three years prior to the date of qualification.

F. The candidate must achieve a passing score on an approved written or oral examination, or must satisfactorily accomplish a "practical examination" by performing a demonstration audit. Results of successful evaluations are retained in the MACTEC, Inc. personnel/qualification files.

G. MACTEC, Inc. may accept Lead Auditor qualification accomplished for another employer engaged in related work activities, upon completion of verification by the corporate QA Manager, or designee.

H. Upon completion of qualification requirements, the candidate is certified as a Lead Auditor by signature of the corporate QA Manager, or designee.

4.3.12 Maintenance of Lead Auditor Proficiency: Each Lead Auditor is evaluated annually to ensure proficiency in conducting and leading audits is maintained.

4.3.13 Requalification for Lead Auditors: Requalification is determined on the basis of at least one of the following criteria:

A. Satisfactory performance of at least one assessment during the preceding 12 months. Evidence of such performance will be by copy of that portion of an assessment report that shows active participation in the audit or reference to such an audit.

B. Review and study of application of codes, standards, procedures, instruction, and other documents related to QA program and program assessment.

C. Participation in required and continuing training programs.

4.3.13 Lead Auditors who fail to maintain their proficiency for a period of two years or more require requalification. Requalification includes retraining in accordance with the requirements of 4.3.8(d), re-examination in accordance with the requirements of 4.3.8(f), and participation in at least one assessment. Personnel records for each Lead Auditor updated annually and maintained in accordance with paragraph 5.0.

4.4 INSPECTION AND TEST PERSONNEL EXAMINERS

4.4.1 NDE Examiners: The corporate QA Manager with the local office QA Coordinator determines the need for MACTEC, Inc. to maintain a Level III NDE examiner. When a need exists, the QA Coordinator designates in writing one or more qualified individuals as the Level III NDE examiner(s). A Level III examiner shall meet the education,

experience, and examination requirements for Level III Sections III and XI of the ASME Code and ASNT-TC-1A for the specific methods to which designated.

4.4.2 A qualified subcontractor may be designated as the Level III NDE examiner, provided the subcontractor submits required qualifications to the QA Coordinator for review and acceptance.

4.4.3 A Level III NDE examiner is qualified to evaluate the qualifications of prospective NDE technicians and certify those individuals meeting the requirements of ASNT-TC-1A.

4.4.4 The QA Coordinator may appoint, in writing, one or more qualified individuals as the MACTEC, Inc. Level II and/or Level III QA examiner(s). A Level III QA examiner shall meet the education, experience, and examination requirements for Level III of the ASME Code, Section XI, or NQA-1, or as required by contract, for the disciplines appointed.

4.4.5 A Level II and/or Level III QA examiner is qualified to evaluate the qualifications of prospective Level I and Level II specialists and technicians and can certify those individuals meeting the requirements of ASME NQA-1, as appropriate.

4.4.6 The QA Coordinator may appoint, in writing, one or more Level II and/or Level III examiner(s) to evaluate the qualifications of technical specialists and engineers.

4.4.7 A Level II and/or Level III examiner can evaluate the qualifications of technical specialists and engineers, as required, and can certify those individuals meeting the requirements of ASME NQA-1, as appropriate.

4.5 ASSESSOR/AUDITOR EXAMINATIONS

4.5.1 MACTEC, Inc. is responsible for the development and administration of the examination for assessors and Lead Auditors. This activity may be delegated to a certifying agency, but MACTEC, Inc. retains responsibility for conformance to applicable requirements. Integrity of examinations is maintained through appropriate confidentiality of files and, where applicable, proctoring of examinations. Objective evidence regarding the type and content of examinations are retained and maintained with personnel qualification records.

5.0 RECORDS

MACTEC, Inc. qualification records are required for:

A. Personnel Qualification (ANSI N45.2.6) – Appendix 2.2.2/2.2.4 (ANSI/ASME NQA-1, Supplement 2S-1).

B. Lead Auditor Qualification (ANSI N45.2.23) – Appendix 2.2.7 (ANSI/ASME NQA-1, Supplement 2S-3).

C. Auditor Qualification (ANSI N45.2.23) – Appendix 2.2.6. (ANSI/ASME NQA-1, Supplement 2S-3).

D. NDE Qualification (SNT-TC-1A) ASME NQA-1 Supplement 2S-2 – Appendix 2.2.3

Qualification and certification records are maintained and controlled in accordance with Section 17 of this manual. MACTEC, Inc. Human Resources maintains records of background employment and education verifications.

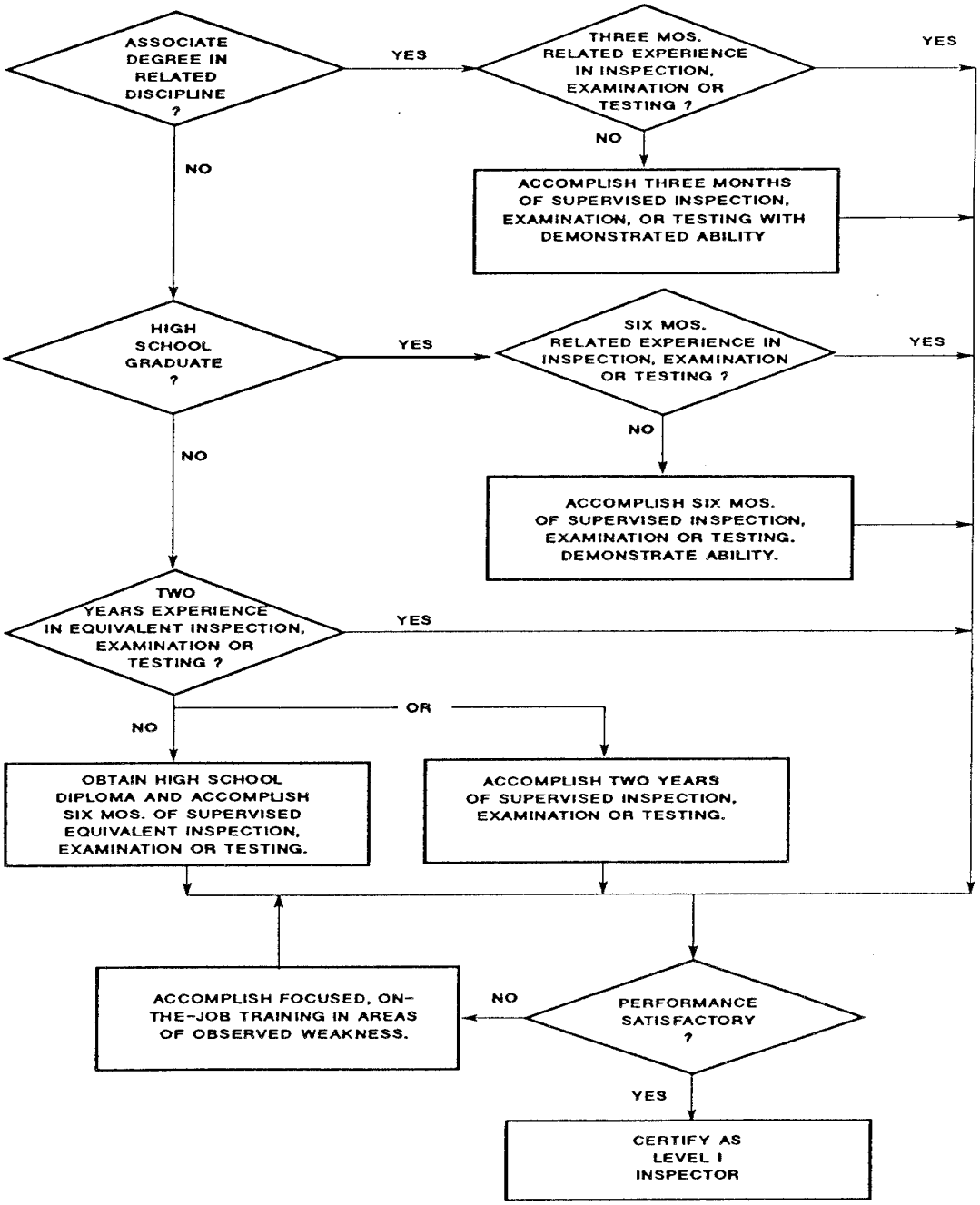
APPENDICES

2.2.1 Qualification Logic Chart
2.2.2 Personnel Qualification
2.2.3 Typical Vision Examination Form
2.2.4 Certification of Qualification
2.2.5 NDE Annual Evaluation Form
2.2.6 Assessor/Auditor Qualification Record
2.2.7 Lead Auditor Qualification

❖ *See Policy Volume 2.0, Qualification and Certification*

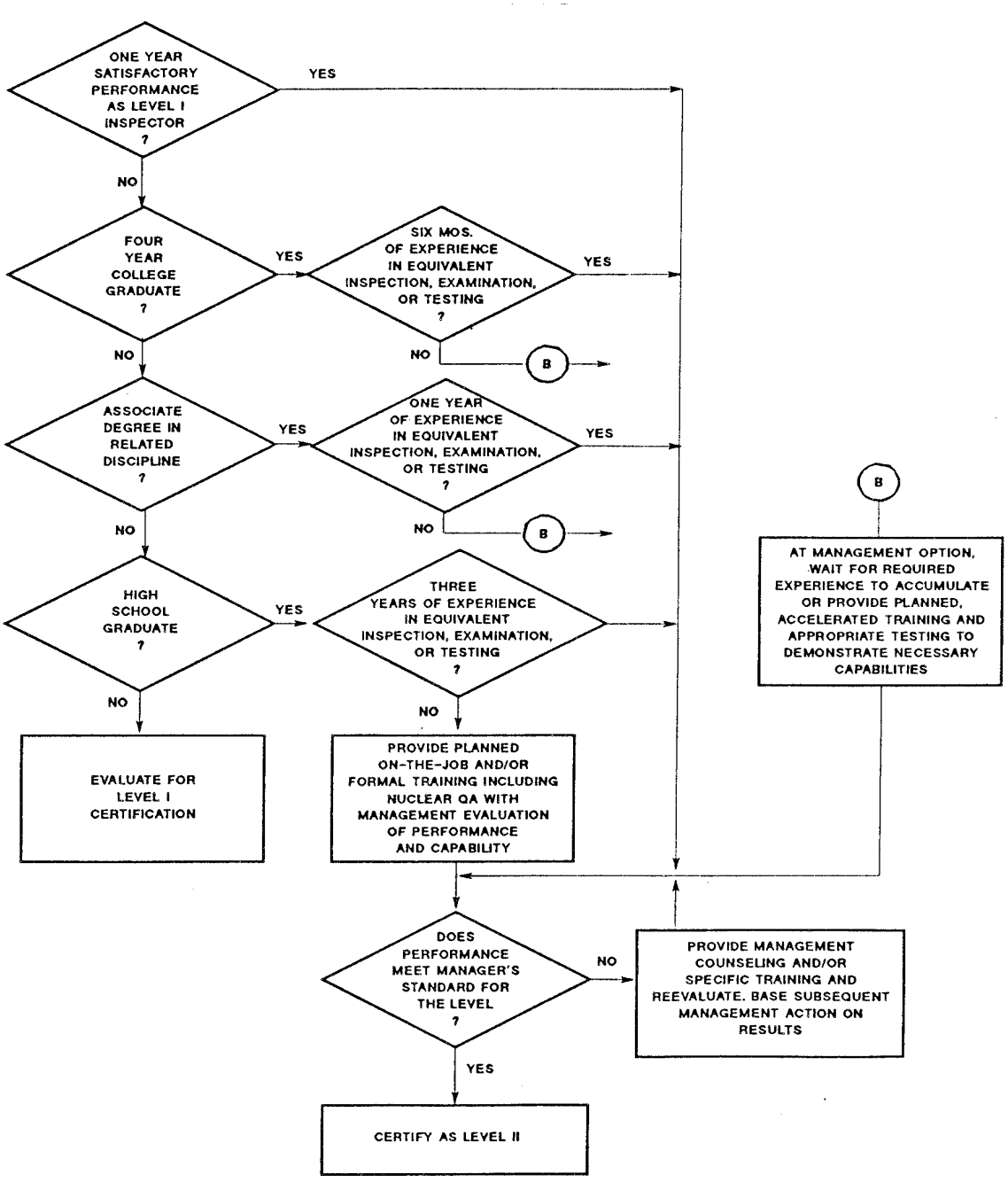
APPENDIX 2.2.1
QUALIFICATION LOGIC CHART

LEVEL I



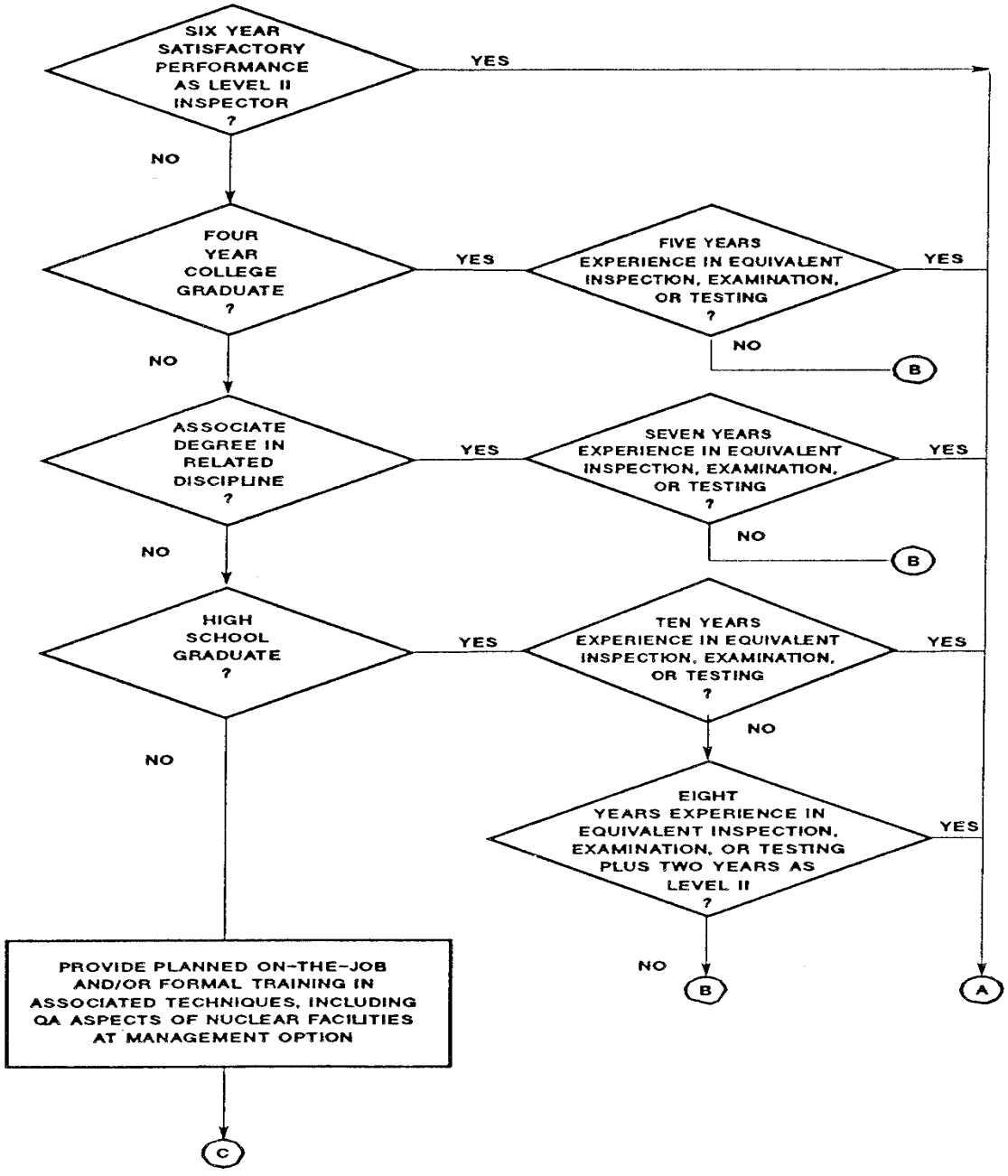
APPENDIX 2.2.1 (Con't)
QUALIFICATION LOGIC CHART

LEVEL II



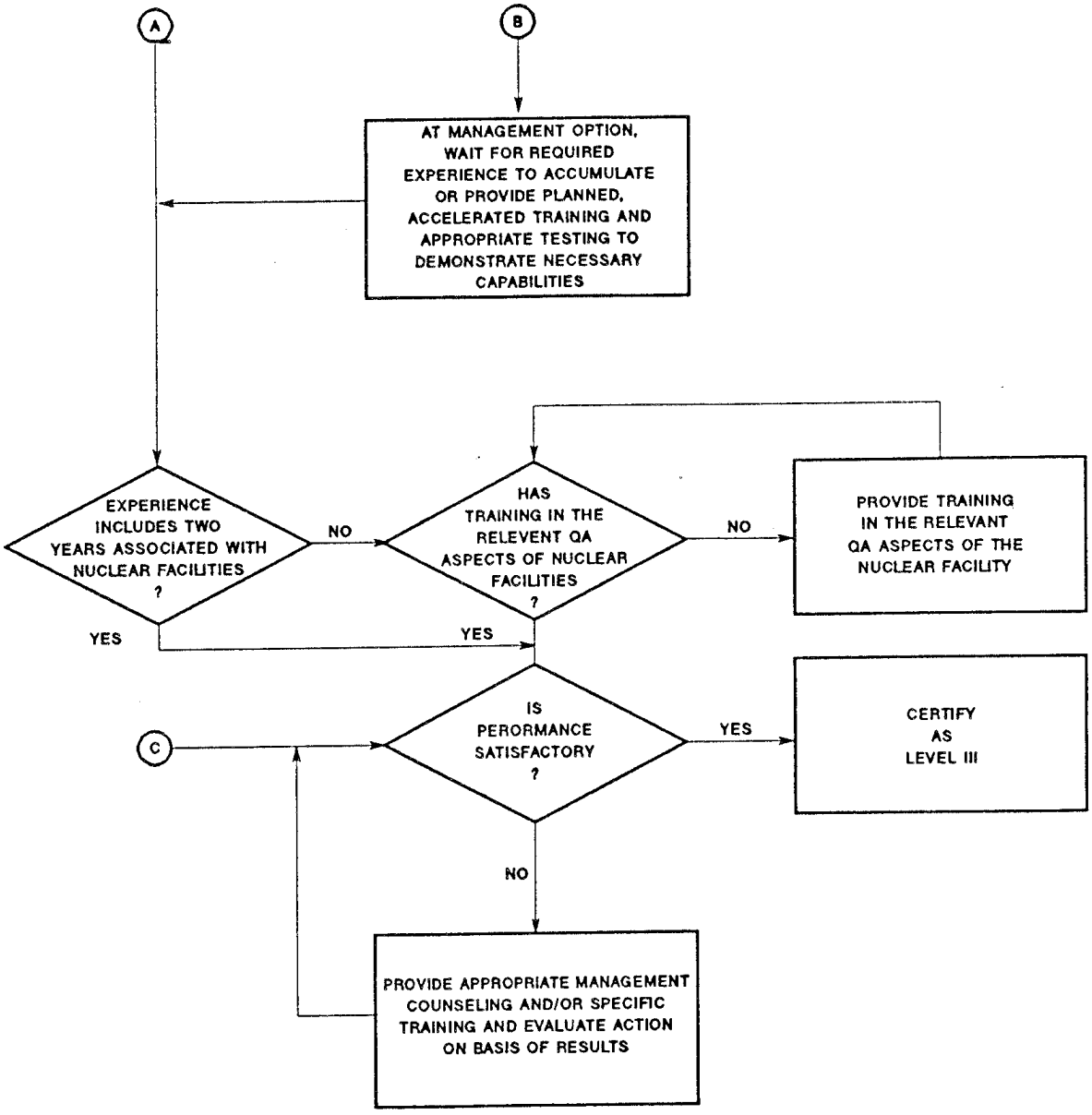
APPENDIX 2.2.1 (Con't)
QUALIFICATION LOGIC CHART

LEVEL III



APPENDIX 2.2.1 (Con't)
QUALIFICATION LOGIC CHART

LEVEL III (continued)



APPENDIX 2.2.2
PERSONNEL QUALIFICATION
(meets requirements of ANSI N45.2.6-1978)
ANSI/ASME NQA-1, 2S-1

INSPECTOR CERTIFICATION
(Per: ANSI/ASME NQA 1-1983/86 and N45.2.6)

INITIAL CERTIFICATION ☐ RECERTIFICATION ☐

EMPLOYEE NAME _____

CAPABILITY LEVEL _____ AREA(S): ELECTRICAL ☐ MECHANICAL ☐
NUCLEAR ☐ INSTR & CONTROL ☐
CIVIL ☐

ACTIVITIES AUTHORIZED TO PERFORM:

Education and experience meet criteria of the MAC Inspector Qualification Logic Chart for LEVEL _____ Inspector. (Evaluator sign: _____) (Required only for initial certification in specified LEVEL.)

	EVALUATOR INITIAL
LEVEL I	
o Proficiency in use of required tools; equipment.	_____
o Familiarity with inspection and measuring equipment calibration and control methods.	_____
o Ability to verify equipment in proper condition for use and procedures.	_____
LEVEL II	
o Ability to supervise/maintain surveillance over inspections and tests.	_____
o Ability to calibrate/verify calibration validity.	_____
o Proficient in planning/setting up tests.	_____
o Ability to determine validity of test results.	_____
LEVEL III	
o Ability to plan/supervise inspections/tests.	_____
o Ability to review/evaluate required procedures.	_____
o Ability to evaluate adequacy of planned inspection, examination, test activities.	_____
o Ability to organize/report results, verify/certify validity of results.	_____

PHYSICAL EXAMINATION (SIGNATURE AND DATE)						
VISUAL ACUITY (SIGNATURE AND DATE)						

Recommend Certification: _____

Recommend Recertification: _____

CERTIFIED BY: _____ DATE _____ EXPIRATION DATE _____

RECERTIFIED: _____ DATE _____

APPENDIX 2.2.3

VISION EXAMINATION			
Name: (Last, First, Middle Initial)		**Social Security Number:**	
Near Distance Vision			
Jaeger No. 1 at 12 inches	***Left*** ***(Cover right eye)***	***Right*** **(Cover left eye)**	***Both***
Uncorrected			
Corrected			
Far Distance Vision			
Snellen Test Chart at 20 feet	***Left*** **(Cover right eye)**	***Right*** **(Cover left eye)**	***Both***
Uncorrected			
Corrected			

Color Vision

A. Has the applicant distinguished the appropriate range and number of color plates to verify normal color vision? ( ) Yes ( ) No

B. What color(s) is the applicant deficient in seeing?_____
_____
_____

C. Remark(s)_____
_____
_____

Summary – Vision Examination Information

A. Test with Glasses – Type Used i.e., Bi-focal, Tri-focal, Contacts_____
B. Type of Test (near distance) ( ) Jaeger ( ) Other_____
C. Type of Test (far distance) ( ) Snellen ( ) Other_____
D. Type of Test (color) ( ) Ishihara ( ) Practical ( ) Other_____

Examiner's Certification of Results

I certify that the results recorded above are those results from the vision examination given to:

(Name)_____ on (Date) _____

MD, RN, etc. (Signature)_____Title _____ Date_____

Quality Assurance Certification

Per the results recorded above, the named individual has ( ) Passed ( ) Failed the vision examination.

Level III Auditor (Signature)_____ Date _____

APPENDIX 2.2.4

CERTIFICATE OF QUALIFICATION

NAME: (Last, First, Middle Initial) Social Security Number:

Level of Certification

☐ Level I ☐ Level II ☐ Level III

Discipline/Method Date of Assignment

Additional Tasks

Task	Basis	Date: From	Date: To	Initials	Date

Restrictions/Limitations

Dates of Certification

From: _____ To: _____

Basis for Certification

☐ Verification of Experience and Education ☐ Oral Exam(s)
☐ Training ☐ Performance Demonstration
☐ Written Exams ☐ Vision Examination
☐ Practical Exams ☐ Other _____
Exam Grade: _____

Certification

I hereby certify the above named individual is qualified to perform inspections/examinations as shown above.

Discipline/Method Level II/III (signature): Date:

Approved by (signature): Date:

APPENDIX 2.2.5

NDE ANNUAL EVALUATION FORM

Name (Last, First, Middle Initial)	Social Security Number

Level of Certification

□ Level I □ Level II □ Level III

Discipline/Method

*Discipline/Method*_____

Date of Current Certification

From: _____ To: _____

Basis for Evaluation

□ Inspection Activities Performed during Previous 12 Months
□ Examination
□ Performance Demonstration
□ Other _____

Objective Evidence of Inspection/Examination Activities

The above-named individual □ has □ has not successfully performed inspections/examinations at the level and in the discipline indicated above and is therefore □ qualified □ not qualified to continue performing work within the certification.

Conducted by: Date: Approved by: Date:

APPENDIX 2.2.6
ASSESSOR/AUDITOR QUALIFICATION RECORD

_____ has satisfactorily completed orientation and training in MACTEC QA assessing and is qualified to participate as an assessor team member. The training consisted of (check applicable boxes):

☐ Review of applicable procedural requirements, regulations, standards, codes, and Section 18-1

☐ Formal Course

☐ Audit Workshop

☐ On-the-job training under the following Lead Assessor(s) or Lead Auditor:

Certified by: _____ Date: ____
Level II/III or Lead Auditor

APPENDIX 2.2.7

LEAD AUDITOR QUALIFICATION FORM

MACTEC, Inc. **1627 Cole Blvd., Bldg. 18** **Golden, CO 80401**	Name:	Date:

Qualification Point Requirements		Credits
Education – University/Degree/Date	-4Credits Max	
1. Undergraduate Level 2. Graduate Level		
Experience – Company/Dates	-9 Credits Max	
Technical (0-5 points) and Nuclear Industry (0-1 point), or Quality Assurance (0-2 points), or Auditing (0-4 points)		
Professional Accomplishment – Certificate Date	-2 Credits Max	
1. P.E. 2. Society	3. Senior Operator License /Certification (2 points) 4. Reactor Operator License/Certification (1 point)	
Management – Justification/Evaluator/Date	-2 Credits Max	
Explain: Evaluated by_____, Corporate QA Manager		
	Total Credits	

Audit Communication Skills				
Evaluated by: _____, Corporate QA Manager			Date:	
Adult Training Courses			Date:	
Course Title or Topic 1. 2.				
Audit Participation				
Location 1. 2. 3. 4. 5.		Audit	Date	
Examination (Signature and Date)		Passed _____, Corporate QA Manager	Date	
Auditor Qualified By: (Signature and Title)				Date Certified
Annual Evaluation (Signature & Date)				

Procedure Title: WORK CONTROL

1.0 PURPOSE

This section establishes requirements and defines the procedure for controlling project work activities to ensure that they comply with the applicable requirements of both the applicable contract and this QA Program.

2.0 SCOPE

The quality requirements of this section apply to MACTEC, Inc.and its subsidiaries when performing project activities.

3.0 GENERAL

3.1 The services provided by MACTEC, Inc. are dependent on the contract involved, but generally relate to: management consulting; project and program management; environment, safety and health management; quality management; information technology; training; plant operations; regulatory and litigation support; maintenance management; design/engineering and engineering management; and construction/construction management. MACTEC, Inc. work is planned, authorized, accomplished, and verified through a controlled process using written instructions, procedures, or other appropriate means. The degree of complexity and detail in instructions and procedures is commensurate with the risk associated with the work being performed.

3.2 The achievement of quality involves the integrated effort of the entire MACTEC, Inc. organization. Individuals assigned to a project are responsible for the quality of the work they perform and for continuously striving for improvement. Project and corporate management have the responsibility to provide the training, resources, and guidance necessary for the accomplishment of the work. Project Managers and local office management at all levels have the important role of setting expectations for quality by creating an atmosphere in which personnel are motivated to perform at their highest level, constantly striving for improvement.

Senior management sets the overall priorities and work objectives for MACTEC, Inc. local offices and their personnel. They establish the corporate and project organizational structures and oversee the preparation and approval of the project plans and budgets required to accomplish the priorities and objectives.

The Project Manager is responsible for planning project work, identifying the requirements imposed on the project, defining acceptable work performance, and ensuring that personnel working under their direction are provided the necessary

direction and feedback on their performance. The project schedule, resources, and budget are considered when developing estimates for planning to ensure expectations can be readily achieved.

Project personnel are responsible for the quality of their work and for ensuring that they have the prerequisite tools and documents necessary for performing assigned tasks. When work instructions are unclear, or when refresher training is needed, individuals should take the initiative to communicate the need for further training or clarification prior to performing work.

4.0 IMPLEMENTATION

4.1 CONTROL OF PROJECT ACTIVITIES

4.1.1 Overall project activities are controlled by the combination of the contract with the client, overall project plan, appropriate procedures and instructions, and the Quality Project Plan, when required (See Section 2-1 and Section 2-4). It is the Project Manager's responsibility to ensure that a Quality Project Plan is developed that is in conformance with the requirements identified by the client contract and MACTEC, Inc. corporate manuals, procedures, and instructions. (Projects of a routine nature and complexity may not require a Quality Project Plan.)

4.1.2 The Project Manager ensures that adequate controls are established for project activities and that project personnel are properly trained, qualified, and have the proper tools available prior to performing the work. In most cases MACTEC, Inc. projects are conducted under the QA programs established by the client. However, the development of project-specific procedures may be required by MACTEC, Inc.

4.1.3 Project plans, procedures, and instructions are prepared with a level of detail commensurate with the complexity and importance of the work or activity. To provide smooth transition in work processes involving more than one organization, process documents, such as the Quality Project Plan and procedures, define organizational interfaces and responsibilities, intermediate process steps, and expectations of the organizations.

4.1.4 Management involvement in the work and work processes keeps management current and creates an environment that encourages employees to improve the quality of the work and work processes. To meet work performance objectives and expectations, each individual must focus on his or her specific tasks and take responsibility for the quality of the work performed.

4.2 DEVELOPMENT/USE OF PROCEDURES

4.2.1 Generally, MACTEC, Inc. projects are performed in accordance with client procedures. Project-unique procedures are prepared only when required.

4.2.2 The Project Manager and QA Coordinator review client procedures to be used to control project activities prior to their use to ensure that the procedures meet the applicable contractual requirements.

4.2.3 Procedures developed for specific projects will comply with the requirements of the client contract and the applicable portions of this manual. As a minimum, the Project Manager and QA Coordinator review and approve new procedures and procedural revisions prior to their use.

5.0 RECORDS

Records generated from implementation of the requirements of this section are maintained in accordance with Section 17-1, Quality Assurance Records.

- *See Policy Volume 2.0, Work Control*

Procedure Title: QUALITY PROJECT PLANS

1.0 PURPOSE

This section establishes requirements for the development of Quality Project Plans (QPP) for MACTEC, Inc. projects. The Quality Project Plan is a formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed meet or exceed the contractual, technical, and quality requirements established by MACTEC, Inc. and the MACTEC, Inc. client.

2.0 SCOPE

The quality requirements of this section are applicable to MACTEC, Inc. and its subsidiaries when project activities are complex; the relative importance of the project products, services, or activities to quality, safety, and health, or safeguards and security; or the client contract requires the development of a Quality Project Plan. A Quality Project Plan shall be prepared for projects that involve implementation of 10 CFR 830, Subpart A, NQA-1, collection and/or analysis of environmental data, laboratory analyses, provision of design services, implementation of a combination of requirements from both the MACTEC, Inc. QA Program and a client QA program, the graded application of QA requirements, or preparation of a formal quality improvement plan.

3.0 GENERAL

3.1 QUALITY PROJECT PLAN ELEMENTS

3.1.1 Quality Project Plans are tools used to support systematic quality planning and the formal documentation of that planning; Quality Project Plans also describe the applicability of the MACTEC, Inc. QA Program to project-specific activities.

3.1.2 Project Managers shall ensure the development of a Quality Project Plan for a specific project.

3.1.3 The Project Manager and the QA Coordinator shall review/approve project-specific QPP's.

3.1.4 QA Project Plans shall provide for the following, as applicable:

A. Definition of the scope of project activities and the associated quality activities.

B. A project-specific organizational chart that identifies the assignment of responsibilities for implementation of QA requirements and project organizational interfaces.

C. Identification of external interfaces.

D. Regulatory and/or other sources of subcontractor QA requirements.

E. Identification of the contractual QA requirements and applicable standards.

F. Documentation of the applicable QA program(s), i.e., the MACTEC, Inc. QA Program, or the client's QA program, or selected elements of each; or, if the project requires the application of QA-related regulations or standards other than those listed in Section 2-1, the regulation or standard and the applicable quality program elements.

G. Identification of the applicable QA program requirements selected from the applicable QA program.

H. Identification of any special processes involved in the project activities.

I. Identification of the approach to a graded application.

J. An index of procedures anticipated to be used during project activities:

1) The index shall include the source of the procedure (i.e., MACTEC, Inc. or client procedures).

2) When client procedures are used, the Quality Project Plan shall define the responsibilities for reviewing the procedures for adequacy for the project.

3) Procedures developed for the project shall be identified and the schedule for their development provided.

K. Definition of the degree of independent verification necessary to assure compliance to project requirements.

L. Project training requirements.

M. The plans and provisions for QA records defined as follows:

1) Project documents that will be classified as QA records shall be identified.

2) The provisions for accumulation, processing, and protection of the QA records during the project shall be identified.

3) The planned disposition of the QA records shall be identified.

3.1.5 Quality Project Plans for certain types of environmental activities typically may require the following elements, as applicable:

A. Project management elements that may include project/task organization, problem definition/background, project/task description, quality objectives and criteria, special training/certification, and project documents and records.

B. Data Generation and Acquisition that may include sampling process design (experimental design), sampling methods, sampling handling and chain of custody, analytical methods, quality control, non-direct measurements, inspection and testing.

C. Assessment and oversight that may include reports to management and assessments and corrective actions.

D. Data Validation and usability that may include data review, verification and validation, verification and validation methods, and reconciliation with user requirements.

3.2 IMPLEMENTATION

3.2.1 The Project Manager and/or QA Coordinator determine(s) the need to develop a Quality Project Plan during the planning stages for a project.

3.2.2 Quality Project Plans include applicable requirements from paragraph 3.1.

3.2.3 Quality Project Plans are prepared in sufficient time for the requirements to be incorporated into the project planning and to support the schedule for project activities.

3.2.4 The Quality Project Plan is identified with the project number on the cover page.

3.2.5 The Quality Project Plan approvals include (as a minimum):

A. The Project Manager

B. The QA Coordinator

C. A government agency, such as the EPA, if required

3.2.6 The Project Manager and/or the QA Coordinator control the Quality Project Plan during the life of the project in accordance with Section 6-1. Any changes must be approved in accordance with the same approval cycle as that of the original Quality Project Plan.

4.0 RECORDS

Records generated from the requirements of this section are maintained in accordance with Section 17-1, Quality Assurance Records.

- *See Policy Volume 2.0, Quality Project Plans*

Procedure Title: DESIGN CONTROL

1.0 PURPOSE

This section is an overview of the design control process and methods contained in the MACTEC, Inc. Design Process Manual, and describes the methods to maintain design control, ensure that applicable regulatory requirements are met, and ensure that the design basis is correctly translated into specifications, drawings, procedures, and instructions. Design control also includes provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from such standards are identified and controlled.

2.0 SCOPE

This section applies to MACTEC, Inc. and its subsidiaries when performing design control activities.

3.0 GENERAL

3.1 RESPONSIBILITY FOR DESIGN CONTROL QUALITY ASSURANCE

MACTEC, Inc. Project Managers shall be responsible for assuring adequacy of design control as it relates to design activities performed by MACTEC, Inc. personnel in accordance with the MACTEC, Inc. Design Process Manual and Quality Project Plans.

3.2 PERFORMING OR ADMINISTERING THE QUALITY ASSURANCE PORTION OF DESIGN DOCUMENT REVIEWS

3.2.1 Quality Assurance for design activities is typically performed using procedural checklists derived from project requirements. The checklists may address only the elements of design control, or may be developed to address the design considerations for a specific discipline (e.g., mechanical, civil, electrical).

3.2.2 The QA portion of design document review may include verification of the following:

A. Specification of design input requirements.

B. Satisfaction or resolution of design input requirements in the design output documents.

C. Documentation of design output and inclusion of appropriate quality standards and/or justification for deviation from such standards.

D. Appropriate qualitative and quantitative acceptance criteria.

E. Technical justification for the suitability of materials selected.

F. Definition and control of design interfaces (both organizationally and by component).

G. Compliance with applicable regulatory requirements.

H. Identification of characteristics essential to safe and proper functioning.

I. Definition of the authority and duties of persons/organizations performing design activities.

J. Verification of design adequacy by technically qualified individuals other than the designer.

K. Provision for control and review of design changes equivalent to the original design. Satisfactory evidence of implementation and effectiveness where applicable.

3.3 DESIGN CONTROL REQUIREMENTS

3.3.1 The Project Manager shall document the specific scope of design activities and the associated responsibilities in the project plan and a Quality Project Plan.

3.3.2 The Quality Project Plan shall describe, at a minimum, the scope and nature of the design/design control activities; the technical and quality interfaces between the MACTEC, Inc. project organization and the design organization(s); the QA requirements that are imposed on the activities; and the implementation of the requirements or a reference to the procedures that define the implementation. See Section 2-4 of this manual for Quality Project Plan development.

3.4 DESIGN INPUT

3.4.1 Design inputs shall be identified and documented and their selection reviewed and approved by the responsible design organization(s) and other organizations in accordance with approved procedures and/or the MACTEC, Inc. Design Process Manual. Design inputs are defined in the MACTEC, Inc. Design Process Manual and typically include those criteria, parameters, bases, or other design requirements upon which the final design is based.

3.4.2 Design inputs shall be appropriately specified and correctly translated into design documents.

3.4.3 Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3.4.4 Changes from approved design inputs, including the reason for the changes, shall be identified, documented, approved, and controlled.

3.5 DESIGN PROCESS

3.5.1 The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.

3.5.2 Design documents shall be adequate to support facility design, construction and operation, and environmental activities.

3.5.3 Appropriate quality standards shall be identified and documented and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, documented, approved, and controlled.

3.5.4 Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component or environmental activities shall be selected and independently reviewed for suitability of application.

3.5.5 Information derived from experience (e.g., prior similar designs, design standards or methods, lessons learned), as set forth in reports or other documentation, shall be made available to cognizant design personnel.

3.5.6 The final design (approved design output documents and approved changes thereto) shall:

A. Be relatable to the design input by documentation in sufficient detail to permit design verification.

B. Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.5.7 Design analyses shall be performed and documented in a planned and controlled manner in accordance with the Design Process Manual.

3.5.8 Design analysis documents shall be legible and in a form suitable for reproduction, microfilming, filing, and retrieval. They shall be sufficiently detailed so as a person

technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

3.5.9 Calculations shall be identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date, or by other data such that the calculations are retrievable.

3.5.10 Computer programs may be used for design analysis without individual verification of the program for each application, provided:

A. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.

B. The encoded mathematical model has been shown to produce a valid solution over the range of application to the physical problem associated with the particular application.

3.5.11 Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on requirement 3.5.10, above.

3.5.12 Documentation of design analyses shall include:

A. Definition of the objective of the analyses.

B. Definition of design inputs and their sources.

C. Results of literature searches or other applicable background data.

D. Identification of assumptions and indication of those that must be verified as the design proceeds.

E. Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.

F. Review and approval.

3.5.13 For environmental activities (e.g., performance of hazardous waste studies, facility permitting and monitoring, and site remediation), the following additional items shall be considered as a minimum:

A. QA objectives for measurement data in terms of precision, accuracy, representativeness, completeness, and comparability shall be defined.

B. Analytical methods and equipment required, including sub-sampling or extraction methods and waste disposal requirements shall be defined, as appropriate.

C. Performance standards as related to analytical methods shall be stated.

D. Sampling procedures including handling and custody in the field, laboratory, and transport, and data quality objectives shall be defined.

E. Data quality objectives (precision, accuracy, representativeness, completeness, and comparability) shall be identified in applicable sampling and analysis plans.

F. The requirements, including limits, for analytical laboratory data reduction, validation, and reporting shall be defined.

G. The extent of analytical laboratory internal QC checks and their frequency shall be defined.

H. Specific routine procedures to be used to assess data precision, accuracy, and completeness of specific measurement parameters that are involved shall be defined.

I. The configuration of computer hardware and software used for environmental data collection and data processing shall be controlled by an approved configuration management system. Configuration changes to either the hardware or software shall be tested as a system in order to detect any adverse effects on the total system operation.

J. Data validation and usability shall be defined including data reviews, verification and validation methods, and reconciliation with user requirements.

3.6 DESIGN VERIFICATION

3.6.1 Design adequacy shall be verified in accordance with approved procedures by one or more of the following:

A. Performance of Design

B. Use of Alternate Calculations

C. Performance of Qualification Tests

3.6.2 Verification of computer software shall include appropriate testing.

3.6.3 The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated.

3.6.4 Design verification shall be performed by any qualified, competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided that the supervisor did not specify a singular design approach, rule out certain design considerations, or establish the design inputs used in the design, or provided that the supervisor is the only individual in the organization competent to perform the verification.

3.6.5 Cursory supervisory reviews do not satisfy the intent of a design verification.

3.6.6 Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases, the design verification shall be completed prior to relying upon the system, component, or structure to perform its function.

3.6.7 The extent of the design verification required is a function of risk assessment, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

3.6.8 Where the design has been subjected to a verification process performed in accordance with the requirements of this procedure, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.

3.6.9 The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design. Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

3.7 CHANGE CONTROL

3.7.1 Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the structure, system, or component are still valid in accordance with the MACTEC, Inc. Design Process Manual.

3.7.2 Environmental activity design changes and field changes shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall assure that the design analyses are still valid and that applicable regulatory permits have not been violated.

3.7.3 Approvals required for design changes shall be specified by the Quality Project Plan.

3.7.4 When an organization which originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated. Responsibility for the designation shall be documented in the Quality Project Plan and/or design change procedures. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent or the original design.

3.7.5 When a significant design change is necessary because of an incorrect design, the original design process and verification procedure shall be reviewed and modified as necessary.

3.7.6 When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

3.8 INTERFACE CONTROL

3.8.1 Physical/functional design interfaces shall be identified and controlled and design efforts shall be coordinated among the participating organizations in accordance with the MACTEC, Inc. Design Process Manual. Physical/functional interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

3.8.2 Design information transmitted across organizational interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items that require further evaluation, review, or approval. When it is necessary to initially transmit design

information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

3.9 AS-BUILT DOUMENTATION

3.9.1 After modification or extensive repair on equipment or systems, there shall be determination that as-built conditions are correctly and completely shown on the drawings, specifications, engineering change notices, and other equipment/systems descriptions.

4.0 RECORDS

4.1.1 Design records include evidence that the design and design verification processes were performed in accordance with the requirements of this manual and the MACTEC, Inc. Design Process Manual, shall be maintained in accordance with Section 17-1 of this manual, Quality Assurance Records.

4.1.2 Records shall include not only final design documents, such as drawings and specifications, and revisions thereto, but also documentation that identifies the important steps, including sources of inputs that support the final design.

Procedure Title: PROCUREMENT DOCUMENT CONTROL

1.0 PURPOSE

This section is an overview of the detailed procurement process and methods contained in the MACTEC, Inc. Procurement Manual, and describes the controls employed by MACTEC, Inc. and its subsidiaries to assure that purchasing documents for items, products, or services within the scope of the MACTEC, Inc. QA Program clearly describe what is required.

2.0 SCOPE

The scope of this section applies to MACTEC, Inc. and its subsidiaries when preparing, reviewing, and approving procurement documents for products or services related to projects.

3.0 GENERAL

3.1 DEFINITION OF REQUIREMENTS

Because of the nature of the majority of projects and the associated procurement activities of MACTEC, Inc. and its subsidiaries, the QA program is not routinely applied to purchases made by MACTEC, Inc. and its subsidiaries. However, when specific projects involve the procurement of quality-related items or services, the necessary controls shall be applied to procurement documents. The application of the requirements contained in this section shall be documented in a project's Quality Project Plan.

3.2 PROCUREMENT DOCUMENT CONTROL

3.2.1 Procurement documents shall be controlled to ensure that applicable requirements, design bases, and other requirements necessary to ensure adequate quality are included or referenced in documents for procurement of material, equipment, and services.

3.2.2 To the extent necessary, procurement documents shall require suppliers to have a QA program consistent with the applicable project requirements. Measures shall be established for the control of procurement documents, such as purchase requisitions/orders, including content, to ensure that only correct and complete procurement documents are used.

3.3 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents shall include provisions for the following:

A. Scope of Work - A statement of the scope of work for services to be performed by the supplier shall be in the procurement documents.

B. Technical Requirements - Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished. The procurement documents shall provide for identification of test, inspection, and acceptance requirements. Requests for proposal packages should include only approved drawings and specifications.

C. QA Program Requirements - Procurement documents shall require that the supplier have a documented QA program that implements applicable QA requirements.

1) The extent of the program required shall depend upon the type and use of the item or service being procured.

2) The quality standard imposed shall be consistent with the type and use of the items or services procured.

3) The supplier shall be requested to submit its QA program manual for evaluation, as required, to MACTEC, Inc and/or its subsidiaries. The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.

4) Right of Access - At each tier of a procurement, the procurement documents shall provide for access to the supplier's plant facilities and records for inspection or audit by MACTEC, Inc., a designated representative of MACTEC, Inc., and/or other parties authorized by MACTEC, Inc..

D. Documentation Requirements - The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by MACTEC, Inc. The time of submittal also shall be established. When MACTEC, Inc. requires the supplier to maintain specific QA records, the retention times and disposition requirements shall also be prescribed.

E. Nonconformances - The procurement documents shall include MACTEC, Inc. requirements for reporting and approving disposition of nonconformances (refer to Section 15-1 of this manual, Nonconforming Materials, Parts, or Components).

F. Spare and Replacement Parts - The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and QA-related data required for ordering these parts or assemblies.

G. Commercial Grade Items - Commercial grade items shall be identified on the purchase order by the manufacturer's published product description (for example, catalog number).

3.4 PROCUREMENT DOCUMENT REVIEW

3.4.1 A review of the procurement documents and changes thereto shall be made to ensure that documents transmitted to the prospective supplier(s) include appropriate provisions to ensure that items or services will meet the specified requirements.

3.4.2 Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such reviews prior to award of purchase order or other similar procurement contract.

3.4.3 Changes made as a result of the proposal evaluations or pre-award negotiations shall be incorporated into the procurement documents. The review of such changes and their effects, including costs and MACTEC, Inc. schedule impacts, shall be completed prior to award. This review shall include the following considerations:

1. Appropriate requirements specified in paragraph 3.3 above.

2. Determination of any additional or modified design criteria.

3. Analysis of exceptions or changes requested or specified by the supplier and determination of the effects such changes may have on the clarity and meaning of the procurement documents, quality of the item or service to be furnished, and impact on competitors.

3.4.4 Reviews shall be performed by personnel who have access to pertinent information, and who have an adequate understanding of the requirements and intent of the procurement documents.

3.4.5 QA Program controls applied for specific items and activities shall be defined using a graded approach.

3.5 PROCUREMENT DOCUMENT CHANGES

3.5.1 Changes to procurement documents that affect quality/technical requirements shall be subject to the same degree of control used in the preparation of the original documents.

3.5.2 MACTEC, Inc. and its suppliers shall ensure that measures to control changes to its prospective procurement documents are established, implemented, and documented. MACTEC, Inc. procurement documents shall be controlled in accordance with Section 6-1 of this manual, Document Control.

4.0 RECORDS

Procurement documentation and records that provide evidence that the procurement process was performed in accordance with the requirements of this manual and the MACTEC, Inc. Procurement Manual shall be maintained in accordance with Section 17-1 of this manual, Quality Assurance Records.

Procedure Title: INSTRUCTIONS, PROCEDURES AND DRAWINGS

1.0 PURPOSE

This section provides the requirements for the content, review, issue, approval and use of instructions, procedures, and design documents to ensure that activities affecting quality are properly performed, and that the product meets requirements.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing activities related to instructions, procedures, and drawings developed and used by MACTEC, Inc. personnel in performance of work under requirements of this QA Manual. When MACTEC, Inc. performs work with instructions, procedures, and drawings furnished by the client, the work shall be performed in accordance with those instructions, procedures, and drawings.

3.0 GENERAL

3.1 QUALITY ASSURANCE MANUAL

3.1.1 The basic description of MACTEC, Inc.'s QA Program is documented in this QA Manual. The individual sections of this QA Manual require approval of the corporate QA Manager and the President and CEO. Requests for changes to the QA Manual shall be submitted to the corporate QA Manager. Such requests shall define the nature of the change, the reason for the change, and/or the objective to be obtained in making the change.

3.1.2 Activities affecting quality shall be prescribed by and performed in accordance with approved requirements documents including instructions, procedures, plans, or design documents of a type appropriate to the circumstances.

A. Instructions, procedures, and design documents used for activities affecting quality shall contain the necessary administrative and technical requirements, as applicable, including the sequence of actions and interactions required to ensure that activities are properly performed and meet requirements.

B. Appropriate acceptance criteria (quantitative and qualitative) for determining if work activities are satisfactorily completed shall be included or referenced.

C. Procedures shall be developed and implemented for appropriate routine, standardized, or special/critical environmental operations. The guidelines in this section shall be used, as applicable, to establish form, content, applicability, and approval.

3.1.3 Documented work instructions (e.g., instructions, procedures, and drawings) shall identify suitable equipment and work environment and include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

3.2 DETERMINATION OF SPECIFIC REQUIREMENTS

3.2.1 MACTEC, Inc.'s knowledge of the QA requirements of regulatory documents, codes, and standards imposes an obligation to assure that client procedures or other instructions, used by MACTEC, Inc. personnel to perform quality-related activities for the client, fully comply with those requirements; that processes, personnel, and equipment are qualified as required; and that appropriate records are maintained of the qualified processes, equipment, and personnel.

3.2.2 The assigned Project Manager and/or QA Coordinator are responsible for determining the need for and providing required work instructions within the scope of the contract. The level of detail of such instructions shall be based on the complexity of the work to be performed and the skills of the workers. Instructions shall be written so that a full understanding of the task by MACTEC, Inc. personnel is assured. The QA Coordinator and/or the Project Manager ensure that the Project Quality Plan identifies these documents.

3.2.3 The instructions shall identify the applicable project, drawing/specification, workmanship criteria, and prerequisites to starting work, and provide properly sequenced steps for work performance, verification, and documentation. When the instructions are written for a client, the format shall be acceptable to the client. When such instructions are for use with this QA Manual, they should follow the guidance of this manual. When such instructions are not specifically required by the client, but are deemed necessary by the QA Coordinator for MACTEC, Inc. personnel, the format shall be acceptable to the Project Manager and/or the QA Coordinator and consistent with the requirements of this paragraph.

3.2.4 Documents affecting quality shall meet the applicable requirements of the latest issue of the contractually required standard. Such documents shall be reviewed by qualified reviewers and approved prior to release. They shall be filed and maintained as quality records.

3.4 CONFORMANCE TO MACTEC, INC. WORK INSTRUCTIONS

Conformance to work instructions by MACTEC, Inc. personnel is mandatory. The Project Manager is responsible for assuring conformance to such documents or obtaining approved changes where compliance is impossible or impractical.

3.5 DOCUMENTS DEVELOPED OR MODIFIED FOR CLIENT USE

3.5.1 Qualified personnel using applicable and appropriate information sources and requirements prepare documents affecting quality that are provided to or modified for the client's use by MACTEC, Inc. These documents shall meet or exceed the client's higher tier QA program requirements and commitments.

3.5.2 The Project Manager and/or the QA Coordinator ensure that qualified individuals review the documents. The reviewers shall include qualified representatives of affected disciplines.

3.5.3 The Project Manager and/or the QA Coordinator shall ensure adequate and appropriate review of specified documents prior to release.

3.5.4 The Project Manager and/or QA Coordinator shall ensure a record of the specified documents provided to the client is maintained, including documented evidence of approval of each document by the client.

3.6 CHECKLISTS

3.6.1 Whenever appropriate for the MACTEC, Inc. task, the Project Manager shall ensure the preparation and use of checklists. Standardized or existing checklists may be used in specific disciplines, such as mechanical, electrical, and civil engineering, when appropriate. Procedures for checklists shall define the approvals necessary to release the checklist for use.

3.6.2 Checklists shall identify the specific project, drawing or specification, applicable revision, characteristics/features to be verified, and provisions for documenting conformance to checklist specifications along with the results of the verification. The checklists shall be provided in a format acceptable to the client.

4.0 RECORDS

Checklists, instructions, procedures, and drawings are quality records and are filed and maintained in accordance with Section 17-1 of this manual, Quality Assurance Records, and/or in accordance with approved procedures.

- *See Policy Volume 5.0, Instructions, Procedures, and Drawings*

Procedure Title: DOCUMENT CONTROL

1.0 PURPOSE

This section describes how MACTEC, Inc. and its subsidiaries implement the measures for ensuring that quality-related documents affecting work activities are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activities are performed.

2.0 SCOPE

The quality requirements in this section apply to documents associated with quality-related work activities performed by MACTEC, Inc. and its subsidiaries. Documents include corporate manuals such as the Procurement Manual, Design Process Manual, and the QA Manual. Additional quality-related documents within the scope of this section include procedures that implement the requirements of the corporate QA Manual and other documents that may result from those procedures.

3.0 GENERAL

3.1 REQUIREMENTS AND RESPONSIBILITIES

3.1.1 Local office QA Coordinators and/or Project Managers are responsible for establishing document control requirements, including those for specific projects, where applicable. These requirements shall control the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that work activities are performed using correct documents. Approved procedures shall be established and shall include, as a minimum, the following:

A. Identification of responsibility for preparing, reviewing, approving, and issuing documents.

B. Controlled documents and changes thereto are reviewed prior to release to ensure that technical and quality requirements are sufficiently, clearly, and accurately stated and authorized.

C. The distinction is made between minor (editorial) revisions and major revisions and any differences in the revision process for those two classifications of documents. Minor revisions shall not require the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor change that does not require such a review and approval and the person(s) who can authorize such a decision shall be clearly delineated.

D. Major changes or revisions are reviewed and approved by the same organization(s) that performed the original review and approval unless other qualified organizations are designated in writing. The reviewing organization shall have access to pertinent background data or information upon which to base its approval.

E. Changes to instructions, procedures, drawings, and other design documents are issued in accordance with the MACTEC, Inc. Design Process Manual.

F. Methods will be established for document revisions and a historical file of the revisions shall be maintained as a quality record.

G. Documents typically are identified on a document index, listing current revisions and changes.

H. Documents are distributed according to an established distribution list to ensure availability at the location where the activity will be performed prior to commencement of work.

3.1.2 Types of documents that are controlled include, but are not limited to, the following:

A. QA Manual
B. Quality procedures/instructions
C. Project procedures/instructions
D. Others as defined in contract documents
E. Design documents as stated in the MACTEC, Inc. Design Process Manual
F. Procurement documents as specified in the MACTEC, Inc. Procurement Manual

3.1.3 Personnel using copies of controlled documents shall verify, prior to use, that the documents are the appropriate versions.

3.1.4 Personnel issued controlled copies are responsible for identification and control of the copies, including identification of obsolete documents "For Reference Only" or for their removal and disposition.

3.1.5 Quality-related documents received from MACTEC, Inc. clients and suppliers shall be reviewed and controlled in accordance with approved procedures.

3.2 MACTEC-ISSUED DOCUMENTS

3.2.1 Documents generated by MACTEC, Inc. in connection with activities and/or contract performance shall be identified by subject, date, and (where applicable) client or contract. Distribution of such documents and changes shall be in accordance with this section or the Quality Project Plan.

3.3 CONTROL OF QUALITY ASSURANCE MANUAL

3.3.1 The corporate Quality Manager is responsible for the preparation, control, revision, and distribution of this Quality Assurance Manual. The Manual contains a Policy Volume, Procedure Volume, and Appendices.

3.3.2 The MACTEC, Inc. Chairman and CEO and the MACTEC, Inc. corporate QA Manager approve the corporate Quality Assurance Manual.

3.3.3 The Policy and Appendix Volumes each contain a revision number and date of issuance. The Procedure Volume is comprised of sections with each section having its own revision number and date or issuance.

3.3.4 When a section of the Procedure Volume is revised, the section is issued in its entirety, indicating a new revision. When the Policy and Appendix Volumes are revised, they are revised in their entirety and issued with a new revision number. Revisions are reviewed and approved in the same manner as the original sections.

3.3.5 Distribution of the Quality Assurance Manual will include an electronic form available to users by way of the MACTEC, Inc. website. Read-only capability will be provided.

3.3.6 The Marketing Support Services office distributes the Quality Assurance Manual and its revisions.

3.4 DEFINITION AND CONTROL OF OTHER DOCUMENTS

3.4.1 The QA Coordinator and/or Project Manager are responsible for maintaining a master list of project-specific documents and applicable revisions for assigned projects. Personnel are responsible for using the current issue of documents, unless otherwise specified.

4.0 RECORDS

Documents become records upon completion of processing. Records are maintained and controlled in accordance with Section 17 of this manual, Quality Assurance Records.

- *See Policy Volume 6.0, Document Control*

Procedure Title: CONTROL OF PURCHASED ITEMS AND SERVICES

1.0 PURPOSE

This section describes the methods MACTEC, Inc. uses to control purchased items, materials and services.

2.0 SCOPE

The quality requirements of this section apply to MACTEC, Inc. and its subsidiaries when performing activities related to purchased item quality-related controls. These activities may include performing evaluations of supplier's abilities to meet requirements, developing qualified supplier listings, investigating supplier issues, performing supplier procurement control operations for the client, and ensuring that purchased products or services conform to specified requirements.

3.0 GENERAL

3.1 PURCHASING MATERIALS, PRODUCT, OR SERVICES FOR CLIENT APPLICATION

3.1.1 When MACTEC, Inc. purchases materials, product, or services for client quality-related applications, quality requirements may be determined by whether the procurement is in accordance with the MACTEC, Inc. or the client QA program.

3.1.2 When the client QA program is applied, applicable parts of the client's QA program will apply. This includes purchasing the services of independent contractors in specific areas of expertise affecting quality. If the material, product, or service is not safety-related, good commercial practice should be applicable.

3.1.3 When the procurement is in accordance with the MACTEC, Inc. QA Program, the requirements of paragraph 4.0 of this section shall apply.

3.2 PURCHASING MATERIALS, PRODUCT, OR SERVICES FOR MACTEC PROJECTS

3.2.1 Procured items and services shall meet established requirements and perform as specified.

3.2.2 The QA Coordinator and/or Project Manager shall document in the Quality Project Plan, and/or other procedures and instructions, the extent of anticipated procurement activities and the portions of this section to be applied to those activities to ensure conformance to specified requirements. Such control shall provide for the following, as appropriate:

A. Source evaluation and selection.

B. Evaluation of objective evidence of quality furnished by the supplier.

C. Source inspection.

D. Examination of items or services upon delivery or completion.

3.2.3 Requirements necessary to ensure adequate quality shall include or referenced in procurement documents and in accordance with the MACTEC, Inc. Procurement Manual.

3.3 PROCUREMENT PLANNING

3.3.1 Procurement activities shall be planned and documented in accordance with the requirements of the MACTEC, Inc Procurement Manual to ensure a systematic approach to the procurement process. Planning should result in the documented identification of procurement methods and organizational responsibilities.

3.3.2 Planning should be accomplished as early as practicable, but no later than the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process.

3.3.3 Planning shall result in the documented identification of methods used for procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of:

A. Procurement document preparation, review, and change control.

B. Selection of procurement sources.

C. Proposal evaluation and award.

D. Control of supplier performance.

E. Verification activities by MACTEC Inc. personnel, including notification for hold and witness points.

F. Control of nonconformances (i.e., items and associated documents).

G. Corrective action.

H. Acceptance of items or services.

I. Quality assurance records.

3.4 SUPPLIER EVALUATION AND SELECTION

3.4.1 Suppliers shall be selected based on an evaluation of their capability to provide items and services that meet the requirements listed in the procurement documents (i.e., purchase order). This evaluation should be made in accordance with established procedures and/or the MACTEC, Inc. Procurement Manual and should be completed prior to award of contract or placement of orders. Selection shall be on the basis of specified criteria.

3.4.2 Procurement source evaluation and selection measures should be implemented by MACTEC, Inc. personnel and provide for identification of MACTEC, Inc. organizational responsibilities for determining supplier capability.

3.4.3 Measures for evaluation and selection of procurement sources, and the results thereof, should be documented and include one or more of the following:

A. Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history should reflect current capability.

B. Supplier's current quality records supported by documented qualitative and quantitative information that can be evaluated objectively.

C. Supplier's technical and quality capabilities as determined by a direct evaluation of the supplier's facilities and personnel, and the implementation of the supplier's QA program.

3.5 PROPOSAL EVALUATION

3.5.1 Proposal evaluation determines the extent of conformance to the procurement documents. This evaluation typically is performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

A. Technical considerations.

B. QA requirements.

C. Qualifications of supplier's personnel.

D. Supplier's production capability.

E. Supplier's past performance.

F. Alternates.

G. Exceptions.

3.5.2 Prior to the award of a contract (e.g., proposal or purchase order), MACTEC, Inc. personnel shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the proposal evaluation.

3.6 SUPPLIER PERFORMANCE EVALUATION

3.6.1 MACTEC, Inc. should establish necessary measures to interface with the supplier and to verify the supplier's performance, when appropriate. The measures typically include the following:

A. Establishing an understanding between MACTEC, Inc. and the supplier of the provisions and specifications of the procurement documents.

B. Requiring the supplier to identify planning techniques and processes used in fulfilling procurement document requirements.

C. Reviewing supplier documents that are generated or processed during activities fulfilling procurement requirements.

D. Identifying and processing necessary change information.

E. Establishing the method of document information exchange between MACTEC, Inc. personnel and supplier.

F. Establishing the extent of source surveillance and inspection activities.

3.6.2 Verification activities shall be conducted as early as practicable. Verification activities, however, should not relieve the supplier of the responsibility for verifying the achievement of quality.

3.6.3 The extent of verification activities, including planning, should be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance.

3.6.4 Verification activities typically are performed by qualified personnel assigned to check, inspect, evaluate, or witness the activities of suppliers.

3.6.5 Verification activities shall conform to requirements of procurement documents and should be documented.

3.6.6 Source surveillances and inspections, receiving inspections, nonconformances, dispositions, waivers, and corrective actions should be documented; MACTEC, Inc. personnel should ensure that this documentation is evaluated to determine the supplier's QA program effectiveness.

3.7 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

3.7.1 Supplier-generated documents shall be controlled and approved in accordance with applicable requirements. The submittal of these documents is accomplished in accordance with the procurement document requirements and provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

3.8 CONTROL OF CHANGES IN ITEMS OR SERVICES

3.8.1 MACTEC, Inc. and the supplier ensure that measures to control changes in procurement documents are established, implemented, and documented, and are in accordance with the MACTEC, Inc. Procurement Manual and/or other applicable requirements.

3.9 ACCEPTANCE OF ITEM OR SERVICE

3.9.1 Methods shall be established for the acceptance of an item or service being furnished by the supplier.

3.9.2 Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with procurement requirements. Where required by code, regulation, or contract requirement, evidence that items conform to procurement documents shall be provided to MACTEC, Inc. personnel.

3.9.3 The MACTEC method(s) used to accept an item or related service from a supplier shall be in accordance with the MACTEC, Inc. Procurement Manual and include supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test, or a combination thereof, as applicable.

A. Certificate of Conformance. When a certificate of conformance is used, the minimum criteria of items "1" through "6" below, shall be met:

1. The certificate identifies the purchased material or equipment, i.e., by the purchase order number.

2. The certificate identifies the specific procurement requirements met by the purchased material or equipment, i.e., codes, standards, and/or other specifications. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

3. The certificate identifies procurement requirements that have not been met, together with an explanation of the means for resolving the nonconformance(s).

4. The certificate is signed, or otherwise authenticated, by a person who is responsible for the supplier's QA function and whose function and position are described in the MACTEC, Inc. or the supplier's QA program.

5. Procedures and instructions for completing a certificate and the administrative procedures for review and approval of the certificate, should be described in the MACTEC, Inc. or the supplier's QA program.

6. MACTEC, Inc. personnel should conduct verification of the validity of supplier certificates and the effectiveness of the certification systems at intervals commensurate with the supplier's past quality performance.

B. Source Verification. Source verifications are performed as deemed necessary and at intervals consistent with the importance and complexity of the item or service; they should be implemented to monitor, witness, or observe activities. Source verification is performed in accordance with plans to perform inspections, examinations, or tests at predetermined points. When source verification is accepted, documented evidence of acceptance typically is furnished by MACTEC, Inc. personnel to the receiving MACTEC, Inc. and supplier personnel.

C. Receiving Inspection. Purchased items are inspected, as necessary, to verify conformance to specified requirements, taking into account source verification activities and the demonstrated quality performance of the supplier. Receiving inspection is performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection should be coordinated with review of supplier documentation when procurement documents require that this documentation be furnished prior to receiving inspection.

D. Post-installation Testing. Post-installation test requirements and acceptance documentation should be mutually established between MACTEC, Inc. personnel and the supplier.

3.10 ACCEPTANCE OF SERVICES ONLY

3.10.1 Procurement of services only, such as third-party inspection, engineering and consulting services, analytical laboratory services, and installation, repair, overhaul, or maintenance work, MACTEC, Inc. will accept the service using any or all of the following methods:

A. Technical verification of data produced.

B. Surveillance of the activity.

C. Review of objective evidence for conformance to procurement document requirements, such as certifications or stress reports.

3.11 COMMERCIAL GRADE ITEMS

3.11.1 When a design uses commercial grade items in safety class/safety significant applications, the following requirements are an acceptable alternative to other requirements:

A. The commercial grade item is identified in an approved design document. An alternate commercial grade item may be used, provided the cognizant design organization provides verification that the alternate commercial grade item performs the intended function and meets design requirements applicable to the replaced item and its application.

B. The item's critical characteristics and acceptance characteristics have been identified.

C. The acceptance method used provides reasonable assurance that the item received is the item that was specified and meets design criteria. Source evaluation and selection, where determined necessary by MACTEC, Inc. personnel based on complexity and importance to safety, shall be in accordance with the requirements of this Section of the QA Manual and the MACTEC, Inc. Procurement Manual.

D. Commercial grade items are identified in the purchase order by the manufacturer's published product description (i.e., catalog number).

E. After receipt of a commercial grade item, MACTEC, Inc. personnel determine the following:

1. Damage was not sustained during shipment.

2. The item received was the item ordered.

3. Inspection and/or testing are accomplished, as required by MACTEC, Inc. to ensure conformance to manufacturer's published requirements.

4. Documentation, as applicable to the item, was received and is acceptable.

3.12 CONTROL OF SUPPLIER NONCONFORMANCES

3.12.1 Methods for disposition of items and services that do not meet procurement documentation requirements are established and documented. These methods include the following:

A. Evaluation of nonconforming items.

B. Submittal of nonconformance notice to MACTEC, Inc. personnel by the supplier as directed by MACTEC, Inc (Appendix 7.1.1, Supplier Disposition Request). These submittals should include supplier-recommended disposition (e.g., accept-as-is or repair) and technical justification. Nonconformance(s) to the procurement requirements or MACTEC, Inc. approved documents, which consist of one or more of the following, shall be submitted to MACTEC, Inc. for approval of the recommended disposition:

1. Violation of a technical or material requirement.

2. Violation of a requirement in a supplier document previously approved by MACTEC, Inc.

3. Nonconformance(s) that cannot be corrected by continuation of the original manufacturing process or by rework.

4. An item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

5. Disposition by MACTEC, Inc. of supplier recommendation.

6. Verification of the implementation of a disposition.

7. Maintenance of records of supplier-submitted nonconformance(s).

4.0 RECORDS

Supplier Disposition Requests and other records generated by this Section of the QA Manual are maintained in accordance with Section 17-1, Quality Assurance Records.

APPENDIX

7.1.1 Typical Supplier Disposition Request

❖ *See Policy Volume 7.0, Control of Purchased Items*

APPENDIX 7.1.1

MACTEC, INC. SUPPLIER DISPOSITION REQUEST

Subcontract No._____ SDR No. _____

(TO BE COMPLETED BY SUPPLIER)

MACTEC, INC. OFFICE LOCATION: Attn: MACTEC, Inc. Subcontract Administrator: _____	SUPPLIER NAME AND LOCATION: Subcontract No: Drawing No. and Revision: Component and Serial No: Part Name and Serial No:

Description of Deficient Condition, Specification, Requirement Not Met, or Interpretation Request:

Previous SDR's listed on this part:	Quantity of Nonconforming parts in same lot for which approval has not been requested:

Supplier's recommended disposition/corrective action being taken to prevent recurrence:

Signature of Authorized Supplier Representative:

_____ _____
Signature Date

Disposition Action:

☐ Approved as Recommended ☐ Disapproved ☐ Or as Below:

_____
Subcontract Administrator/Project Manager

This request requires installation or inspection at job site:

☐ Yes ☐ No

Approval: Other Approval (as required):

_____ _____ _____ _____
Project Manager Signature Date Signature Date

The supplier accepts full responsibility for the accuracy and completeness of the above information. The issuance and acceptance of this request in no way limits or affects the warranty provisions of the order. The request shall not establish a precedent or obligation to accept similar conditions in the future.

Procedure Title: IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

1.0 PURPOSE

This section describes methods for the proper identification, traceability, and control of materials, parts, and components including partially fabricated assemblies.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when furnishing items to clients and when performing activities relating to the identification and control of items. Except for those conditions where MACTEC, Inc. and/or its subsidiaries are contractually required to furnish hardware or computer software items to a client, the identification and control of these items typically should be in accordance with client procedures.

3.0 GENERAL

3.1 IDENTIFICATION, TRACEABILITY, AND CONTROL

3.1.1 The Project Manager and/or QA Coordinator should ensure that the Quality Project Plan and/or other written procedures and instructions are established for the identification, traceability, and control of materials, parts, and components, including partially fabricated assemblies or sub-assemblies. These documents can be furnished by MACTEC, Inc. or the client, and should include requirements for, but not limited to, the following, as appropriate:

A. When practical or required by codes, standards, or contractual documents, identification should be maintained on items or in documents traceable to them and should ensure that identification is established and maintained.

B. Preventing the use of defective, unapproved, incorrect or incomplete materials equipment, and precluding use of items whose shelf life or operating life has expired.

C. Unique identification and traceability of items by serial number, part number, batch, lot, or heat number, or specified inspection, test, records, or other appropriate means.

D. Production of an item at any stage from initial receipt through fabrication, installation, repair, modifications, and use can be traced to records such as applicable drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, certified material test reports, or other pertinent applicable design specifying documentation.

E. Permanent physical identification on an item itself to the maximum extent possible, in a manner and location that will not impair or negate its intended use, quality, function, or service life; use of physical separation, procedural control, or other appropriate means where physical identification on the item is impractical or not sufficient.

F. Correct identification of materials, parts, and components verified and documented on appropriate release documents, work packages, or controlling documents, and on materials prior to subdividing an item or material, and prior to release for fabrication, assembly, shipping, and installation.

G. Provisions for control of item identification consistent with the planned duration and condition of storage and fabrication/assembly activities, such as:

- Provisions for maintenance or replacement of identification records due to damage during handling or aging.

- Protection of identifications on items subject to excessive deterioration due to environmental exposure.

- Provision for transferring identification markings to each part of an identified item when subdivided and ensuring that they are not obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

- Provisions for updating existing records as required

3.2 VERIFICATION

3.2.1 Verification of identification and control of items should include the following requirements, as appropriate:

A. Ascertain from design, procurement, and/or process documents the correct unique identification of the item at the stage of process when MACTEC, Inc. responsibility begins.

B. Document that the appropriate identification is applied by the prescribed method for that stage of the process.

C. Document that appropriate identification is maintained for each stage and condition of production up to and including the point of delivery to the client or cessation of MACTEC, Inc. responsibility.

D. Report material, items, or components found without proper identification or control measure in accordance with procedures and do not knowingly use, install, or assemble materials or items which do not conform to requirements.

4.0 RECORDS

Design, procurement and process documents related to the proper identification of items furnished by MACTEC, Inc. are maintained in accordance with Section 17-1, Quality Assurance Records.

- *See Policy Volume 8.0, Identification and Control of Materials, Parts, and Components*

Procedure Title: CONTROL OF SPECIAL PROCESSES

1.0 PURPOSE

This section describes the control of special processes applicable to MACTEC, Inc. services for special processes. Special processes are those processes, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. Therefore, these processes require monitoring to determine compliance with documented procedures and to ensure that requirements are met.

2.0 SCOPE

The quality requirements in this section apply to activities relating to the control of special processes performed by MACTEC, Inc. and/or its subsidiaries. The activities may include those related to environmental work, concrete, welding, cleaning, flushing, coatings, preservation, and performing nondestructive examination services.

3.0 GENERAL

3.1 PROCESS CONTROL

3.1.1 Processes affecting the quality of items and/or services are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means to ensure that process parameters are controlled within defined limits and that specified environmental conditions are maintained.

3.1.2 Methods for defining how process controls may be applied include:

A. Defining process parameters and their limits, including the measurement method(s) used to determine the actual parameters.

B. Specifying use of test pieces and intervals for their use to measure process effects.

C. Specifying physical standards for comparison, as acceptance criteria, of process results.

3.1.3 Qualified personnel perform activities related to special processes that control or verify quality, such as those used in welding, heat treating, nondestructive examination, and laboratory analysis of environmental samples. Personnel should be qualified in accordance with Section 2-2 of this manual. Personnel involved in welding or welding inspection tasks are qualified in accordance with AWS, ASME, and/or client requirements as appropriate for the task.

3.1.4 For special processes not covered by existing codes and standards, or where quality requirements specified for an item, or product, exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment are specified in the Quality Project Plan or procedures and/or instructions

3.2 VERIFICATION OF REQUIREMENTS

3.2.1 Prior to the start of direct work for a client, the Project Manager and/or QA Coordinator verify that client QA provisions, procedures, and documented work instructions for the special processes to which MACTEC, Inc. personnel will be working, are consistent with applicable requirements of the governing regulations, codes, and standards, or brought into compliance, or that the use of procedures developed by MACTEC, Inc. is authorized for work performed by MACTEC, Inc. personnel.

3.2.2 As a minimum, such requirements include provisions for ensuring that special processes are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, or other special requirements.

4.0 RECORDS

Records for qualified processes, equipment, and personnel are maintained in accordance with Section 17-1 of this manual, Quality Assurance Records.

❖ *See Policy Volume 9.0, Control of Special Processes*

Procedure Title: INSPECTION, EXAMINATION, SURVEILLANCE, AND TESTING

1.0 PURPOSE

This section sets forth the requirements for performance of inspections, surveillances, and tests required to verify conformance of items, activities, and services to specified requirements.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing inspection and surveillance activities that are performed under the MACTEC, Inc. QA Program. This section does not apply when inspections and surveillances are performed by MACTEC, Inc. in accordance with client procedures; however, procedures can be developed for a specific client or project application that follow the requirements of this section of the QAM.

3.0 GENERAL

3.1 IDENTIFICATION OF INSPECTION REQUIREMENTS

3.1.1 Inspection requirements and acceptance criteria include specified requirements as contained in applicable design documents or other technical documents approved by the cognizant design organization.

3.1.2 Inspection activities are documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. The combined efforts of project managers, engineers, or technical leads are essential elements of the work planning process used to identify the processes and items to be inspected or tested. This includes the parameters or characteristics to be evaluated, the techniques used, acceptance criteria, hold points, and identification of personnel responsible for performing the tests and inspections.

3.2 INSPECTION PLANNING

3.2.1 Project Managers and/or QA Coordinators ensure the performance of integration, coordination and oversight of inspection and test activities under their purview.

3.2.2 The QA Coordinator, or designee, provides assessment and monitoring of the implementation of inspections and test activities and ensures compliance to approved implementing procedures.

3.2.3 Identification of implementing procedures to control and perform tests and inspections and the personnel responsible for performing the tests and inspections shall be identified.

3.2.4 Inspections that verify conformance of an item or activity to requirements are planned and executed in accordance with the plan.

3.2.5 Acceptance criteria is typically derived from the following:

A. Approved drawings, procedures or instructions
B. Specifications
C. Industry standards
D. Operating technical specifications
E. Design output documents, or
F. Scope of work documents for services

3.3 INSPECTION HOLD POINTS

3.3.1 Specific hold points are indicated in appropriate documents, when mandatory inspection hold points are required (beyond which work shall not proceed without the specific consent of the designated representative).

3.3.2 Inspection hold points shall, as appropriate, be established and documented in consideration of operations, maintenance, and construction activities to minimize scheduling impacts.

3.3.3 Consent to waive specified hold points are recorded prior to continuation of work beyond the designated hold point.

3.3.4 Consent to waive hold points is made by the organization that established the hold point.

3.4 SAMPLING

3.4.1 Sampling procedures used to verify acceptability shall be based on recognized standard practices.

3.5 RECEIVING INSPECTION AND TESTING

3.5.1 Historical data, documents, equipment, or other work product supplied by a client shall be evaluated for suitability and approved prior to use.

3.5.2 Similarly, work products provided by subcontractors shall be inspected for suitability for use and approved prior to use.

3.5.3 Analytical laboratory results supplied by subcontractors shall undergo formal data validation, verification or review prior to release, when required by a project Quality Project Plan or the project-specific statement of work**.**

3.5.4 Field personnel receiving purchased materials shall inspect and approve the materials for conformance to project requirements prior to use.

3.5.5 When circumstances require the release of a product for use prior to inspection, the use of that unapproved product shall be documented in project records for future reference.

3.6 IN-PROCESS INSPECTION

3.6.1 Inspections of items in-process or under construction are performed where necessary to verify quality. Indirect control by surveillance of processing methods, personnel, and equipment is used when inspection of processed items is disadvantageous or impossible. Inspection and surveillance are used together when control is inadequate without both.

3.6.2 When used, a combination of inspection and process monitoring methods are performed in a systematic manner to ensure that throughout the duration of the process, the specified requirements for control of the process and quality of the item are being achieved.

3.6.3 When required, controls are established and documented for the coordination and sequencing of activities at established inspection points during successive stages of a process or construction.

3.6.4 For in-process inspections of large orders, items are identified as deficient as they are discovered; however, no deficiency document is usually written until the inspections of the entire order, lot, type, etc. is complete. Items in this category may be identified as such by using tagging, shrink-wrap, roping off, etc.

3.7 FINAL INSPECTIONS

3.7.1 The requirements for final reviews (i.e., follow-up phase quality control reviews) of completed work product and client deliverables to ensure acceptance criteria have been met shall be specified.

3.7.2 No work product may be released until specified final inspection and test requirements have been met.

3.7.3 Completed items are inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics, as required, to verify the quality and conformance of the item to specified requirements. QA records are examined for completeness.

3.7.4 Final inspections include a records review of the results and resolution of nonconformances identified by prior inspection(s). The final inspection is planned to arrive at a conclusion regarding conformance of items to specified requirements.

3.7.5 Modifications, repairs, or replacements of items performed after final inspection are re-inspected or re-tested to verify acceptability.

3.8 IN-SERVICE INSPECTIONS

3.8.1 Required in-service inspection or surveillance of systems, components, or structures are planned and executed by or for MACTEC, Inc. These inspections verify that characteristics of an item continue to remain within specified limits. Inspection methods include, as appropriate:

A. Evaluation of performance capability of essential emergency and safety systems and equipment.

B. Verification of calibration, and integrity of instruments and instrument systems.

C. Verification of maintenance.

3.9 DOCUMENTATION AND ACCEPTANCE

3.9.1 Inspection results and the acceptance of those results are documented and approved by authorized personnel.

3.10 INSPECTION RECORDS

3.10.1 Records shall, as a minimum, identify:

A. Item inspected
B. Date of inspection
C. Inspector
D. Type of observation
E. Results or acceptability
F. Reference to information or action taken regarding nonconformances

3.11 SURVEILLANCES

3.11.1 Independent surveillances of activities affecting quality, safety, and the environment are planned, scheduled, performed, documented, reported, and followed-up to assure that identified deficiencies are corrected in a timely manner.

3.11.2 Procedures governing the planning, scheduling, performing, documenting, reporting, and follow-up of surveillances are established, maintained, and implemented.

3.11.3 Procedures governing the qualification of personnel who perform surveillances are established, maintained, and implemented in accordance with Section 2-2 of this manual. These procedures specify the minimum education, training, experience,

capability demonstrations (e.g., examinations and practical exercises), and other appropriate criteria required for qualification.

3.11.4 The qualification of personnel is documented and verified prior to performing surveillance functions. The only exception is when on-the-job training for qualification includes participation in the performance of surveillances; however, these surveillances are performed under the direct observation and supervision of qualified personnel.

3.11.5 Surveillance plans and schedules shall be developed with consideration of those processes and activities that would most benefit from surveillance, their regulatory impact, their safety, quality, and environmental significance, and their previous history. Consideration should be given to other inspection, audit, and assessment efforts to avoid duplication and to optimize resources.

3.11.6 Surveillance of environmental activities shall be scheduled, planned, and conducted. Surveillance of the sampling, monitoring, and analytical measurement system, including associated administrative and work control activities shall be scheduled and conducted throughout the course of the work activities. Additional surveillances may be performed when required as part of corrective action.

3.11.7 Surveillances are performed as planned and scheduled by qualified personnel who are independent of the activity being reviewed.

3.12 SURVEILLANCE REPORTING/FOLLOW-UP

3.12.1 Specifications for the format and content of surveillance reports are established, maintained, and implemented.

3.12.2 Surveillance results are documented and reported to responsible management.

3.12.3 Adverse conditions identified during the performance of surveillances are evaluated, tracked, corrected, verified, and closed.

4.0 RECORDS

Records are maintained in accordance with Section 17 of this manual, Quality Assurance Records.

- *See Policy Volume 10.0, Inspection, Examination, Surveillance, and Testing*

Procedure Title: TEST CONTROL

1.0 PURPOSE

This section describes test control activities performed by MACTEC, Inc. and its subsidiaries.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing activities relating to test control of quality-related items.

3.0 GENERAL

3.1 TEST REQUIREMENTS

3.1.1 Tests requiring conformance of an item or computer program to specified requirements and tests to demonstrate satisfactory performance of a service should be planned and executed. These tests can include, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, operational tests, post-maintenance testing, and tests required to collect data, such as for siting or design input. The tests shall be controlled and documented.

3.1.2 Test requirements and acceptance criteria shall be identified, documented, and approved by the responsible design organization unless otherwise designated.

3.1.3 When an organization performs its own acceptance testing, personnel within the organization shall not test their own work.

3.1.4 For tests involving the participation of more than one support group, one individual shall be identified to take responsibility for coordinating the appropriate personnel to perform the testing, review results, and take corrective action, as necessary.

3.1.5 Characteristics to be tested shall be based upon specified test requirements and acceptance criteria contained in applicable design documents, codes, standards, or other pertinent technical documents.

3.1.6 Test methods to be employed shall be identified when testing is required as: (1) a condition for the acceptance or operation verification of items, materials, or equipment; or (2) as part of the construction of new facilities or installations; specific acceptance test procedures may consist of industry accepted test methods (e.g., ADTM) or may be developed and approved.

3.1.7 When testing equipment that is important to safe and reliable facility operation, tests are conducted only in accordance with approved procedures.

3.1.8 The types of test equipment used, such as instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment, shall be defined in the test procedure.

3.1.9 Test equipment shall be of the required precision and accuracy and shall be calibrated and maintained in proper operating condition.

3.1.10 Operating instructions for unique or complex testing equipment may be maintained as an independent document or as executable steps in the specific test procedure using the equipment.

3.1.11 Test results shall be documented, and a responsible authority shall evaluate the results for conformance with acceptance criteria to ensure that test requirements have been satisfied.

3.1.12 Conditions under which retesting is permitted or required shall be defined when applicable.

3.1.13 Test status shall be identified as required by Section 14-1 of this manual, "Inspection, Test, and Operating Status."

3.2 TEST PROCEDURES/INSTRUCTIONS

3.2.1 Test procedures/instructions, as a minimum, should provide a clear identification of the test to be performed, purpose of the test, test boundaries, related drawings and specifications, prerequisites for test performance, step-by-step instructions for performing the test, identification of normal/off-normal conditions to be observed, callouts for test performance and data verifiers, instructions for all actions necessary to return and document the return of affected systems to the normal operable condition, and acceptances and performance criteria. The procedures/instructions also should provide precautions and instructions for lock-out, tag-out, try-out, lifted leads, and equipment checks to ensure correct and safe operation before, during, and after testing, as appropriate.

3.2.2 Test procedures/instructions, plans, and other documents defining test requirement and acceptance criteria shall be reviewed and approved, and consistent with the requirements of governing regulations, codes, and standards.

3.2.3 Test procedures/instructions shall consider the following:

A. Test objectives.

B. Provisions for ensuring prerequisites for a given test have been met. Test prerequisites should include calibrated instrumentation; appropriate equipment; trained personnel; safety barriers/devices/equipment; condition of test equipment and item to be tested; suitable environmental conditions; and provisions for data collection, as applicable.

C. Safety instructions relevant to the test being performed.

D. Configuration of the item to be tested. That is, the required condition of the item being tested should be defined or described.

E. Test requirements and, when applicable, acceptance limits, including precision and accuracy.

F. Training and personnel qualification requirements.

G. Instructions for performing the test.

H. QA/QC hold points, witness points, or verification points, if required.

I. Provisions for performing necessary monitoring.

J. Provisions for adequate test equipment and instrumentation to be available and used.

K. Provisions for maintaining suitable environmental conditions.

L. Acceptance and rejection criteria, including required levels of precision and accuracy.

M. Methods of data analysis.

N. Methods for documenting or recording test data and results.

O. Post-test conditions, if applicable.

3.2.4 In lieu of specially prepared written test procedures/instructions, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions or approved drawings, or travelers (including revisions) with acceptance criteria, may be used. When used, these standards should be readily available to personnel performing the work. Such

documents or document combinations should include adequate instructions to ensure the required quality of work.

3.3 TEST RECORDS

Test records should identify:

A. Item tested.

B. Date tested.

C. Tester (name of individual(s) performing the test) or data recorder.

D. Type of observation.

E. Identification of the applicable technical procedure(s) and revision(s).

F. Description of any known conditions that adversely affected the results of the test.

G. Test results and acceptability.

H. Identification of measuring and test instruments used and their calibration date and calibration due date.

I. Any deviation experienced during conduct of the test and the action taken in connection with the noted deviation.

J. The signature of the person evaluating the test results and the date the evaluation was complete.

K. Identification of any nonconformance report or other deficiency documentation initiated as a result of the test.

3.4 COMPUTER PROGRAM TESTING REQUIREMENTS

3.4.1 Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

3.4.2 Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows:

A. Hand calculations.

B. Calculations using comparable proven programs.

C. Empirical data and information from technical literature .

3.4.3 Testing for computer programs used for operational control shall demonstrate required performance over the range of operation of the controlled function or process.

3.4.4 Depending on the complexity of the computer program tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules. These tests shall be followed by an overall computer program test.

3.4.5 Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

3.4.6 Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

3.4.7 Test problems shall be run whenever the computer program is installed on a different computer or when significant hardware or operating system configuration changes are made.

3.4.8 Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance.

3.5 COMPUTER TEST PROCEDURES

3.5.1 Test procedures or plans shall specify the following:

A. Required tests and test sequence.

B. Required ranges of input parameters.

C. Identification of the stages at which testing is required.

D. Criteria for establishing test cases.

E. Requirements for testing logic branches.

F. Requirements for hardware integration.

G. Anticipated output values.

H. Acceptance criteria.

I. Reports, records, standard formatting, and conventions.

3.6 COMPUTER TEST RECORDS

3.6.1 Verification test records shall be documented and shall identify the following:

A. Computer program tested.
B. Computer hardware used.
C. Test equipment and calibrations, where applicable.
D. Date of test.
E. Tester or data recorder.
F. Simulation models used, where applicable.
G. Test problems.
H. Results and acceptability.
I. Action taken in connection with any deviations noted.
J. Person evaluating test results.

3.6.2 In-use test results shall identify:

A. Computer program tested.
B. Computer hardware used.
C. Test equipment and calibrations, where applicable.
D. Date of test.
E. Acceptability.

3.6.3 Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

4.0 RECORDS

Test records generated from the requirements of this section are maintained in accordance with the requirements of Section 17-1 of this manual, "Quality Assurance Records."

❖ *See Policy Volume 11.0, Test Control*

Procedure Title: CONTROL OF MEASURING AND TEST EQUIPMENT

1.0 PURPOSE

This procedure describes the requirements for the control and calibration of measuring and test equipment that is used in the performance of inspections and examinations to assure that these devices are of the proper range, type, and accuracy to verify conformance to established requirements. MACTEC, Inc. typically subcontracts services for the control and calibration of measuring and test equipment.

2.0 SCOPE

The quality requirements of this section apply to MACTEC, Inc. and its subsidiaries when performing activities to ensure that equipment used is properly calibrated and identified and acceptable for use.

3.0 GENERAL

3.1 REQUIREMENTS AND RESPONSIBILITIES

3.1.1 Measuring and test equipment used by MACTEC, Inc. personnel shall be identified and controlled in accordance with the requirements of this QA Manual and/or a client's QA program.

3.1.2 When commercial practices provide adequate accuracy for the application, measuring and test equipment, such as rules, tape measures, levels, and similar devices, the equipment is not subject to the requirements of this section.

3.1.3 Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and, at specified periods, calibrated and adjusted to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

3.1.4 The cognizant Project Manager and/or QA Coordinator shall ensure that the following requirements are met for measuring and test equipment used by MACTEC, Inc. personnel:

A. The measurements to be made and the accuracy required are defined, equipment of appropriate precision and accuracy is provided, and assigned personnel are knowledgeable of proper environment and equipment usage to ensure accuracy of results.

B. Measuring and test equipment is handled, preserved, stored, used, and safeguarded in a manner that maintains its accuracy and fitness for use.

3.2 CALIBRATION

3.2.1 Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, or when the accuracy of the device or equipment is suspect, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, it is satisfactory to document the bases for calibration.

3.2.2 The calibrating organization shall identify each piece of measuring and test equipment by assigning a unique identification number to the equipment. A record of the calibration of each piece of equipment shall be maintained on a Calibration Log stored with the instrument and in a master file. A separate sheet is used for each piece of equipment. Calibration records include the following:

A. Description of device

B. Identification number of device

C. Procedure used to perform the calibration

D. Allowable tolerance

E. Date of calibration

F. Frequency of calibration

G. Next due date

H. Name/company of calibrator

I. As-found condition/As-left condition

J. Identification of reference standard used (S/N or National Institute of Standards and Technology test number)

Where production tooling, test hardware, or software is used for inspection, they are checked and rechecked periodically to demonstrate their capability for verifying product acceptability.

3.2.3 The frequency of calibration and the tolerances used in the calibration shall be based on manufacturers' recommendations, the frequency of use, and stability of the equipment experience and regulatory/code requirements. The frequency of calibration of each piece of equipment shall be established and documented on each Calibration Log. As an economic or practical option, the frequency of calibration may be established as "prior

to each use" of the equipment subject to calibration. When this option is used, the calibration record discussed in 3.3.1 must reflect this alternative under the "frequency of calibration" entry.

3.2.4 Controlled measuring and test equipment shall be identified by a method showing its calibration status (e.g., a decal sticker showing the serial number, date calibrated, calibration due date, and the initials of the individual performing the calibration or color code or other means uniquely traceable to the specific instrument). The decal sticker also shall identify the name of the laboratory or company performing the calibration. When the decal sticker cannot easily be placed on the device, it should be placed on the device's container.

3.2.5 It is the responsibility of the user of the measuring and test equipment to assure that the instrument is in serviceable condition and that the calibration due date has not expired.

3.2.6 When measuring or test equipment is out of calibration, damaged, inoperative, or suspected of having been damaged, it shall be removed from service, reported, and identified as NONCONFORMING. Such items shall be identified or segregated and not used until they have been recalibrated. Out of calibration devices shall be tagged or segregated and not used until they have been recalibrated. An evaluation of the validity of previous inspections or test results and of the acceptability of items previously inspected or tested should be performed and documented. When measuring or test equipment is consistently found to be out of calibration, it will be repaired or replaced.

3.2.7 Calibrations shall be performed in accordance with written instructions. These instructions shall identify the required number of tests or checkpoints to be measured and that the actual values are recorded.

3.2.8 Calibrations shall use standards traceable to the National Institute of Standards and Testing where such standards exist. For standards not traceable to the National Institute of Standards and Testing, appropriate industry-accepted standards or practices shall be used and documented.

3.2.9 The identification number of all measuring and test equipment used in the performance of inspections or examinations shall be recorded on the inspection or examination report to provide traceability of the use of the equipment.

3.3 MACTEC, INC. USE OF CLIENT EQUIPMENT

3.3.1 When MACTEC, Inc. services require the use of measuring or test equipment provided by the client or the client's contractors, MACTEC, Inc. personnel shall assure such equipment is identified as currently being within a properly approved calibration cycle

and is in good operating condition. MACTEC, Inc. personnel should promptly notify the client if any such equipment could prejudice the acceptance of inspection or test results.

3.3.2 When MACTEC, Inc. personnel find damaged or faulty equipment, evaluations shall be made and documented, and re-inspections performed as required by client procedures.

3.3.3 Measuring and test equipment shall be properly handled and stored to maintain accuracy.

3.4 PREVENTIVE MAINTENANCE

3.4.1 The calibrating organization should perform preventive maintenance for measuring and test equipment on a regular schedule depending on the equipment and manufacturer's recommendations.

3.4.2 Preventive maintenance should include basic cleaning and operational checks performed by qualified individuals or factory service technicians.

3.4.3 Maintenance and operational checks may coincide with scheduled calibrations.

4.0 RECORDS

Records are maintained in accordance with Section 17-1, Quality Assurance Records; equipment shall be suitably marked to indicate calibration status.

❖ *See Policy Volume 12.0, Control of Measuring and Test Equipment*

Procedure Title: HANDLING, STORAGE, AND SHIPPING

1.0 PURPOSE

This section describes the implementation responsibilities for the control of material and equipment handling, storage, shipping, cleaning, and preservation.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing work activities on specific contracts in the areas of handling, storage, and shipping to client-specified procedures.

3.0 GENERAL

3.1 HANDLING, STORAGE, AND SHIPPING

3.1.1 The Project Manager and/or QA Coordinator shall review and approve applicable documents for adequacy and sufficiency of quality requirements and inspection instructions.

3.1.2 When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) are specified, provided, and their existence verified.

3.1.3 When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservations are prepared and meet requirements.

3.1.4 Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

3.1.5 Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.

3.1.6 Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established, as necessary, to adequately identify, maintain, and preserve the items, including identification of the presence of special environments or the need for special controls.

4.0 RECORDS

Records generated from this section are maintained and stored in accordance with written procedures and/or Section 17-1 of this manual, Quality Assurance Records.

- *See Policy Volume 13.0, Handling, Storage, and Shipping*

Procedure Title: INSPECTION, TEST AND OPERATING STATUS

1.0 PURPOSE

This section describes the MACTEC, Inc. implementation responsibilities when applied to quality-related inspection, test and operating status activities.

2.0 SCOPE

The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing activities involving inspection, test, and operating status.

3.0 GENERAL

3.1 INSPECTION AND TEST ACTIVITIES

3.1.1 Standard inspection and testing activities at MACTEC, Inc. consist of receiving inspection, technical reviews, and testing of partial and completed work product at different stages.

3.1.2 The reporting requirements of inspection, test, and operating status activities are typically described in project-specific procedures and/or the Quality Project Plan.

3.1.3 The status of inspection and test activities shall be identified either on the work product or component, or in documents traceable to the item.

3.1.4 Status indicators are intended to prevent inadvertent use of operation of the work product or its components, and include stamps, tags, shop travelers, inspection records, equipment labeling, and physical location of components, or other suitable means.

3.1.5 The authority for application and removal of status indicators shall be specified.

4.0 RECORDS

When records are generated as a result of inspection, test, and operating status activities, they are maintained in accordance with Section 17-1 of this manual, Quality Assurance Records

- *See Policy Volume 14.0, Inspection, Test, and Operating Status*

Procedure Title: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

1.0 PURPOSE

This section describes the requirements, responsibilities and procedures for the preparation and processing of a Nonconformance Report (Appendix 15.1.1) relating to the control of nonconforming materials/items to ensure the following:

A. Dispositions of nonconforming items or data are made with due regard for functional adequacy, safety and economy.

B. Appropriate corrective action is taken.

C. Records are prepared and maintained to show that as-built configuration and that the disposition of any nonconforming item or data was systematically made by cognizant personnel in appropriate fields.

D. Inadvertent use of nonconforming items or data is prevented.

2.0 SCOPE

2.1 The quality requirements in this section apply to MACTEC, Inc. and its subsidiaries when performing tasks involving the reporting of nonconforming materials, parts, or components.

3.0 GENERAL

3.1 REQUIREMENTS

3.1.1 The Project Manager and/or QA Coordinator should ensure that activities are performed in accordance with approved procedures or a QPP.

3.1.2 Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls should provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items.

3.1.3 Processes, services, or activities that do not conform to specified requirements shall be controlled, such that the output of the process, service, or activity is contained. This containment includes identification, documentation, disposition, and correction (when the disposition of nonconforming conditions is rework or repair).

3.1.4 Non-dispositioned items shall not be released for shipment.

3.1.5 Organizations affected by the nonconforming process, item/product, service, or activity shall be notified.

3.1.6 When the reporting of defects and noncompliances is regulated by federal and/or state requirements, such as nuclear facilities licensed and regulated by the NRC, the reporting shall be accomplished in accordance with ***Procedure 1*** located on the MACTEC, Inc. website, Lighthouse, and titled ***Reporting Deficiencies, Defects, or Noncompliances – Federal Regulation 10CFR21, Section 206***, or similar, for other type projects and/or facilities regulated by the federal government or state(s).

3.1.7 In the event material/data authorized inspectors propose dispositions exceeding their authority, the proposed dispositions should be escalated to the QA Coordinator and/or Project Manager. Should the QA Coordinator and Project Manager disagree with the recommended disposition, the corporate Quality Manager should be notified with proposed alternate courses of action together with the appropriate rationale that may include a technical evaluation for making a decision.

3.2 IDENTIFICATION

3.2.1 Nonconforming items are marked, tagged, or identified by other methods that do not adversely affect the end use of the item. The identification should be legible, easily recognizable, and shall remain in place until removed by authorized personnel. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified or noted in a log.

3.2.2 The output of a nonconforming process, service, or activity is identified by having the responsible inspection person or the QA Coordinator complete a Nonconformance Report (NCR) for documentation (see Appendix 15.1.1).

3.3 SEGREGATION OF NONCONFORMANCE ITEMS

3.3.1 Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until the items are properly dispositioned.

3.3.2 When segregation is impractical or impossible because of physical conditions such as size, weight, or access limitations, other precautions should be taken to preclude inadvertent installation or use of a nonconforming item.

3.4 EVALUATION, DISPOSITION AND RE-EXAMINATION OF ITEMS

3.4.1 Nonconforming characteristics shall be reviewed, and recommended dispositions of nonconforming items should be proposed and approved by authorized personnel.

3.4.2 Further processing, delivery, installation, or use of nonconforming items shall be controlled pending an evaluation and an approved disposition by authorized personnel.

3.4.3 The disposition, such as use-as-is, reject, repair, return-to-vendor, or rework of the nonconforming item is documented on an NCR (Appendix 15.1.1).

3.4.4 Technical justification for the acceptability of a nonconformance that is dispositioned as repair or accept shall be documented.

3.4.5 Nonconformances dispositioned as repair or accept shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, should reflect the accepted deviations.

3.4.6 Repaired or reworked items shall be re-examined in accordance with applicable procedure(s) and with the original acceptance criteria, including retesting when appropriate, unless the nonconforming item disposition has established alternate acceptance criteria.

4.0 RECORDS

Records, including Nonconformance Reports, are maintained and controlled in accordance with Section 17 of this manual, Quality Assurance Records.

APPENDIX

15.1.1 Typical Nonconformance Report

- *See Policy Volume 15.0, Nonconforming Materials, Parts, or Components*

Appendix 15.1.1
TYPICAL NONCONFORMANCE REPORT

NCR No. (1)_____
Page (2)__X___ of __Y___
Rev. (3)_____

MACTEC, INC.
NONCONFORMANCE REPORT

(4) Project No./Name:	(5) Mo. / Day / Yr	(6) Part No. Item/Dash No/CL	(7) Part/Material Name	(8) Specification No.
(9) Inspection Area:	(10) Responsibility: ☐ Supplier _____ ☐ MACTEC, Inc. _____			
(11) Lot Size:	(12) Quantity Inspected:	(13) Quantity not Accepted:	(14) Inspection Criteria: ☐ Drawing. ☐ Spec. ☐ SWR/WR ☐ Other I.D. No.:_____	
(15) Name of Supplier/Location		(16) ☐ P.O. ☐ Req. ☐ Subcontract No. _____ Item No. _____		
(17) Material Furnished by: ☐ MACTEC, Inc. ☐ Sponsor ☐ Other		(18) Previous NCR Number: _____		

(19) Discrepancy or Nonconformance		(23) Disposition/Comments	
No:	List in Order: Specification Req./Inspection Results	Review Decisions	(26) Inspector Stamp/Name

(20) Inspector: _____ Date: _____	(21) QA Coordinator: _____ Date:_____	(22) Responsible Engineer or Design Representative Name (optional): _____ Date: _____	
Re-Inspection / Accept No:	Not Accept No.	(27) Inspector Identity/Date	New NCR No.

CORRECTIVE ACTION

(24) Corrective Action Required: ☐ Yes ☐ No	(25) Document Reference

Appendix 15.1.1
TYPICAL NONCONFORMANCE REPORT (continued)

NCR No. (1)____________
Page (2)__X___ of __Y___
Rev. (3)________________

MACTEC, INC.
NONCONFORMANCE REPORT
(Continuation Sheet)

(4) Project No./Name:	(5) Mo. / Day / Yr	(6) Part No. Item/Dash No/CL	(7) Part/Material Name	(8) Specification No.
(9) Inspection Area:	(10) Responsibility: ☐ Supplier ____________ ☐ MACTEC, Inc. ____________			
(11) Lot Size:	(12) Quantity Inspected:	(13) Quantity not Accepted:	(14) Inspection Criteria: ☐ Drawing. ☐ Spec. ☐ SWR/WR ☐ Other I.D. No.:____________	
(15) Name of Supplier/Location		(16) ☐ P.O. ☐ Req. ☐ Subcontract No. ________ Item No. ________		
(17) Material Furnished by: ☐ MACTEC, Inc. ☐ Sponsor ☐ Other		(18) Previous NCR Number: ____________		

(19) Discrepancy or Nonconformance		(23) Disposition/Comments	
No:	List in Order: Specification Req./Inspection Results	Review Decisions	(26) Inspector Stamp/Name

Appendix 15.1.1
TYPICAL NONCONFORMANCE REPORT (CONT'D)

Instructions for Preparing the Nonconformance Report

Number	Instructions
(1)	Enter the unique NCR number obtained from the QA Coordinator or Inspector.
(2)	Designate number of pages.
(3)	Enter NCR revision letter, if applicable.
(4)	Designate the project number.
(5)	Enter the origination date of NCR.
(6)	Enter discrepant part number, data package, etc., including dash number and change letter.
(7)	Designate item or data identifier.
(8)	Enter specification number when applicable.
(9)	Denote area in which discrepancy was found.
(10)	Place a check in a box to indicate responsibility for discrepancy.
(11)	Enter quantity of items affected.
(12)	Enter number of pieces or quantity of items/data inspected. If sampling inspection is used, enter sample size.
(13)	Enter number of pieces or data items found discrepant.
(14)	Place a check in the appropriate box indicating document(s) used as inspection criteria and identification number.
(15)	Enter the supplier's name and location as indicated on purchase order, subcontract, or purchase requisition. This applies only for source and receiving inspection.

Appendix 15.1.1
TYPICAL NONCONFORMANCE REPORT (CONT'D)

Instructions for Preparing the Nonconformance Report

Number	Instructions
(16)	Place a check in the appropriate box to indicate type of procurement document and part number of discrepant part of material. This applies only for source and receiving inspection.
(17)	Place a check in the appropriate box to indicate the source of furnished material.
(18)	Enter, if applicable, the previously prepared NCR number when discrepancy data are transferred or related to a previous NCR.
(19)	Discrepancy or Nonconformance "No." Column. Enter the identification of each discrepancy in numerical sequence. Description of Discrepancy. Enter the number of material or data items discrepant; the specification or purchase order/subcontract requirement; and the inspection results. Space the entries of the individual discrepancy line items such that there are sufficient lines from the end of one item entry to the beginning of the next to provide adequate space for the corresponding disposition entry.
(20)	When finished making entries, the authorized inspector signs and dates the NCR. Note: Nonconforming items should be marked or tagged, or identified by other methods that do not adversely affect the end use of the item. The identification should be legible, easily recognizable, and should remain in place until removed by authorized personnel. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, should be identified or the discrepancy should be noted in a log.
(21)	The QA Coordinator signs and dates the NCR after checking the NCR for completeness, correctness, and legibility of the entries made by the authorized inspector.
(22)	The name of the responsible engineer or authorized design representative may be entered in the space provided.

Appendix 15.1.1
TYPICAL NONCONFORMANCE REPORT (CONT'D)

Instructions for Preparing the Nonconformance Report

Number	Instructions
(23)	The responsible person performing the preliminary material review should enter the disposition in the space provided. When the disposition requires rework, reference the specific portion of the applicable work-planning document to be used. When the disposition requires repair, provide the directions for the repair work and its inspection. Append to this entry sketches, diagrams, or any other aids that clarify the repair disposition. A separate document providing repair instructions may be prepared; in this case, reference the document and append it to the NCR.
(24)	The responsible person should check the appropriate box to indicate if further corrective action is necessary.
(25)	When applicable, indicate the document reference in the space provided.
(26)	If reinspection/retest is required subsequent to rework or repair, circle the affected discrepancy numbers.
(27)	Authorized material inspectors should stamp and date the NCR in the space provided adjacent to the disposition indicating compliance with the disposition.
(28)	When items on the NCR have been dispositioned, the authorized inspector signs and dates the NCR and/or prepares new NCR's for items that remain defective and unsuitable for use, based on reinspection/retest after the original disposition was implemented.
(29)	The QA Coordinator, or designee, should notify affected organizations when the NCR process is complete. Tags or other type identifiers should be removed from dispositioned items and marked as acceptable.

Procedure Title: CORRECTIVE ACTION

1.0 PURPOSE

This section describes how MACTEC, Inc. implements the measures used for ensuring that significant conditions adverse to quality are promptly identified, documented, reported to management, and corrected to preclude repetition.

2.0 SCOPE

2.1 The quality requirements of this section apply to MACTEC, Inc. and its subsidiaries when initiating action to correct significant conditions adverse to project/task quality and/or the QA program as identified by QA audits, inspections, or surveillances conducted by or for MACTEC, Inc. management.

NOTE: In accordance with Federal Regulation 10CFR21, Section 206, instructions for potentially reportable nuclear-related deficiencies, defects, or noncompliances are located on the MACTEC, Inc. website, Lighthouse. Click on the Corporate Manual section for the document titled REPORTING NUCLEAR-RELATED DEFICIENCIES, DEFECTS, OR NONCOMPLIANCES - FEDERAL REGULATION 10CFR21, SECTION 206

3.0 GENERAL

3.1 CORRECTIVE ACTION SYSTEM

3.1.1 Significant conditions adverse to quality shall be identified promptly and corrected as soon as practical. Conditions adverse to quality include failures, malfunctions, deviations, defective material and equipment, abnormal occurrences, nonconformances, and/or those conditions resulting in a programmatic breakdown of the QA program.

3.1.2 The cause of the condition shall be determined and corrective action taken to preclude recurrence.

3.1.3 The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to the cognizant MACTEC, Inc. company manager and the MACTEC, Inc. Corporate QA Manager. Follow-up action shall be taken to verify implementation of this action.

3.2 CORRECTIVE ACTION DOCUMENTATION

3.2.1 A Corrective Action Request (CAR) shall be used to document those nonconformances and deficiencies identified by an audit or surveillance (See Appendix 16.1.1 for an example of a typical CAR).

3.2.2 A CAR is considered closeable after the following steps are addressed and completed:

A. The CAR is reviewed to determine if it is in accordance with program requirements.

B. CARs are issued to the responsible organization and tracked to ensure appropriate action in a timely manner.

C. The responsible organization's response to the CAR contains a clear statement of corrective action, including actions to be taken on items affected prior to discovery of the adverse condition, and a statement of probable cause. Actions to prevent recurrence are included on the CARs.

D. Committed actions have been accomplished and verified.

3.2.3 CARs must not be closed until an acceptable corrective action has been verified and documented as complete by the QA Coordinator/Auditor.

3.2.4 Actions to correct MACTEC, Inc. deficiencies are the responsibility of the MACTEC, Inc. Manager immediately in charge of the function in which the action is required.

3.2.5 Each QA Coordinator is responsible for maintaining an orderly file of audit findings and nonconformances related to applicable MACTEC, Inc. services and for ensuring that the cause of each deficiency is determined, documented, corrected and verified complete.

3.2.6 The Corporate QA Manager shall periodically review and evaluate customer complaints forwarded by the QA Coordinators, and shall review MACTEC, Inc. corrective action effectiveness. This evaluation will encompass the actions taken in Paragraph 3.3 and will include advising the affected management, including the MACTEC, Inc. CEO when appropriate, if adverse trends are noted that require further remedial action.

3.3 CORRECTIVE ACTION ACTIVITIES

3.3.1 The QA Coordinator and/or the cognizant Manager(s) are responsible for coordinating specific activities relating to a Corrective Action Request. These activities include the following, as a minimum:

A. Determining which individual or organization is responsible for corrective action, for requesting investigation(s), and for documenting the corrective action.

B. Reviewing and approving the corrective action responses.

C. Providing assistance in investigations when requested by an involved individual.

D. Performing follow-up to ensure that corrective measures are implemented.

3.3.2 The responsible individual or organization receiving the CAR will be accountable for the following, as a minimum:

A. Determining the method for resolving the CAR.

B. Conducting an investigation into the cause of the incident or condition.

C. Documenting the proposed corrective action on the CAR form and returning it to the QA Coordinator and/or the Manager for review and approval.

D. Implementing approved corrective action within the approved timeframe.

3.3.3 The Manager and/or the QA Coordinator, who are responsible for assuring that as a minimum the requirements of the client contract and of this procedure are met, review identified deficiencies. The QA Coordinator evaluates corrective action suggestions and assures that such suggestions are appropriately addressed either by implementation by MACTEC, Inc. or resolution with the client/MACTEC, Inc. organization.

3.3.4 The QA Coordinator periodically reviews and evaluates MACTEC, Inc. corrective action effectiveness. This evaluation includes informing the Corporate QA Manager, when appropriate, if adverse trends are noted that require further remedial action.

4.0 RECORDS

Completed MACTEC, Inc. CARs are considered quality records and are maintained in accordance with 17-1 of this manual, Quality Assurance Records.

APPENDIX

16.1.1 Typical Corrective Action Request

- *See Policy Volume 16.0, Corrective Action*

Appendix 16.1.1
Typical Corrective Action Request

CORRECTIVE ACTION REQUEST
(1) To _____ (2) From _____ (3) CAR No..... Date ..... Audit Report No.....
(4) Description of Finding Potentially Reportable..... (6) Reported By _____ (5) Accuracy Acknowledged .....
(7) Recommended Action
(8) Committed Action
(9) Scheduled Completion Date _____ (10) Name _____ Title _____ Date.....
Accepted By (11) Name _____ Title _____ Date.....
(12) This space is for follow-up and close-out (13) Closed By _____ Title _____ Date.....

Appendix 16.1.1
Typical Corrective Action Request (Cont'd)

INSTRUCTIONS FOR COMPLETING CORRECTIVE ACTION REQUESTS

Number	Instructions

(1) Enter the name of the organization responsible for investigating the problem.

(2) Enter name, title, and organization of the person making the request, or others as appropriate.

(3) Obtain a CAR number from the Corporate QA Manager and then enter that CAR number, date of finding, audit report number, nonconformance report number or other document numbers, as applicable.

(4) Enter a detailed description of the problem(s). Include identification of requirements with which a variance has been established.

(5) Signature (and date) of originator.

(6) Signature (and date) of representative who can attest to the finding(s); this is the responsible investigator.

(7) Include recommendation(s) that, if implemented, would correct and/or preclude the repetition of the identified condition. The recommendation(s) should be clearly stated to permit the responsible organization to either accept the recommendation(s) as the COMMITTED ACTION, or be used as a basis against which to judge the adequacy of an alternate COMMITTED ACTION.

(8) Include corrective action commitments obtained from the responsible organization. These commitments shall be mutually acceptable to both the QA Coordinator and the responsible organization. Committed actions may consist of, but not be limited to, the following:

a. Process Deficiencies: Identification of new or revised process documents to be used, including descriptions of new documents and/or changes to existing documents.

Appendix 16.1.1
Typical Corrective Action Request (Cont'd)

INSTRUCTIONS FOR COMPLETING CORRECTIVE ACTION REQUESTS

Number **Instructions**

b. Non-compliances to the Existing Programs or Processes: Description of actions to be taken to achieve and verify compliance, including identification of documentation to be submitted as evidence that actions have been completed (e.g., an internal audit report, inspection report, etc.).

(9) Enter date responsible organization has agreed to complete the COMMITTED ACTION.

(10) Enter name and title of individual completing item (10) followed by the date.

(11) Enter name and title of the requesting organization, indicating concurrence or acceptance of the COMMITTED ACTION (adjacent to the name, include signature) followed by the date of the signature.

(12) Include verification by the originating organization of completion of the corrective action.

(13) Enter name and title of the responsible person who closed the CAR (adjacent to the name, include signature) followed by the date of the signature.

NOTE: Additional information may be incorporated by use of continuation sheets. If used, include "Page X of Y" in upper right-hand corner of the CAR form with "of" followed by the number of the last page of the total CAR.

Procedure Title: QUALITY ASSURANCE RECORDS

1.0 PURPOSE

This section describes the requirements for records control, maintenance, storage and retention to demonstrate achievement of quality requirements contained in this manual.

2.0 SCOPE

The quality requirements of this section apply to employees of MACTEC, Inc. and its subsidiaries who generate quality records that are either retained by MACTEC, Inc. or turned over to the client.

3.0 GENERAL

3.1 QA RECORDS

3.1.1 This section ensures that records are:

A. Created, identified, and inventoried, when required by contract.

B. Indexed as directed by the working file records file indices contained in Quality Project Plans.

C. Logged into project databases, if appropriate and available.

D. Protected against loss and damage, deterioration, and theft.

E. Stored and retrieved efficiently.

F. Transferred to permanent storage when the records become inactive.

G. Disposed of according to applicable requirements, procedures, and retention schedules.

3.1.2 Each local office shall establish quality records management processes appropriate to MACTEC, Inc. and their client requirements in accordance with this section.

3.1.3 Project Managers and QA Coordinators shall ensure that project quality records are identified in project working records file indexes and/or records sections of applicable Quality Project Plans.

3.1.4 Office managers should identify the quality records generated by office administrative practices and procedures.

3.1.5 Both office and project records shall be easily retrievable.

3.1.6 The level of control, maintenance, storage and retention specified for a quality record shall be commensurate with the importance of the record, the level of risk if the record is lost or destroyed, and/or the designation of the record as either lifetime or nonpermanent (see 3.4 below, Records Identification and Indexing). Records of high and medium importance shall be protected from damage, deterioration, or loss, including theft, to a greater extent than records having lesser importance.

3.1.7 Quality records of high importance are those whose loss or damage would be critical to performance, and include MACTEC, Inc. and project records requiring stringent protection and handling, or records falling under the most stringent quality classification. Records of medium importance include records whose loss or damage would have an adverse effect on implementation of tasks, and may include project records and suppliers' records. Records requiring minimum protection and preservation are most types of office administrative records.

3.1.8 A review process shall be specified to ensure records are accurate and complete, legible, identifiable, authenticated, and reproducible (e.g., suitable for microfilming or photocopying). The review process shall include verification reviews of completed documents.

3.2 RECORDS GENERATION

3.2.1 Specific procedures shall identify the quality records they generate, and describe the manner in which the records are dispositioned and retained, or, at a minimum, provide the title of the procedure under which the records are controlled in accordance with Section 5-1 of this Quality Assurance Manual. A quality record shall be traceable to an item or activity to which it applies.

3.2.2 Project contractual documents shall identify the quality records required of MACTEC, Inc. suppliers.

3.3 RECORD VALIDATION

3.3.1 Record*s* shall be signed to indicate review/ approval, or otherwise authenticated, and dated. Stamps or initials are acceptable in place of signatures, if local office personnel maintain a list or log of stamps or initials. No handwritten signatures are required when a document is clearly identified as a statement by the reporting party, such as electronic records.

3.3.2 Records may be originals or reproduced copies.

3.4 RECORDS IDENTIFICATION AND INDEXING

3.4.1 Records are classified for retention purposes as either nonpermanent or lifetime (see descriptions below).

3.4.2 Nonpermanent records are those records approved for disposal after a specified retention time. Appendix 17.1.1 provides an example of suggested retention times for nonpermanent records. Typical nonpermanent records include extra copies of documents maintained only for the convenience of reference on which no action is recorded or taken, publications or other processed documents that require no action and are not part of a case on which action is taken, routing slips and transmittal sheets that do not add new information to that contained in the transmittal material (e.g., concurrences, direction on how to proceed or implement), and library and reference materials, such as Navy codes.

3.4.3 Lifetime records are those records defined in the transaction of business, both government and private industry, as evidence of the MACTEC, Inc. offices, organizations, functions, policies, decisions, procedures, operations, or other activities, because of the value of the data in the records. Lifetime records are retained for the life of the item/system or as specified by contract or required regulatory requirements.

3.4.4 The indexing system should provide sufficient information to permit identification between the record and the item or activity to which it applies. The indexing system shall include, as a minimum, record retention times and the location of the record within the record system.

3.5 RECORDS RETENTION

3.5.1 For records that must meet required regulatory retention requirements, such as certain environmental records, and for records retention specified in contracts, MACTEC, Inc. shall comply. In such cases, a project's Quality Project Plan shall specify the retention periods and the custodian of these records. See Appendix 17.1.1 for a typical example of suggested retention times.

3.5.2 When regulatory or contractual retention times are indefinite, QA Coordinators should periodically review the requirements for retention changes and/or changes in business needs.

3.5.3 Unless otherwise specified by contractual requirements, retention of records should be the owner's responsibility following turnover of the records by MACTEC, Inc.

3.5.4 Suppliers or other organizations performing work for MACTEC, Inc. shall maintain quality records related to work performed for the company or client in a manner consistent with the contractual requirements.

3.6 CORRECTING RECORDS

3.6.1 Corrections to quality records shall be marked to show the date and identification of the person making the correction.

3.7 RECORDS STORAGE, PRESERVATION AND SAFEKEEPING

3.7.1 Local office management and personnel responsible for quality records and for receiving quality records shall provide protection from damage or loss during the time that the records are in their possession.

3.7.2 Records shall be stored in a predetermined location(s) that meets the requirements of applicable standards, codes, and regulatory agency and/or client requirements, when applicable; the storage facility shall minimize the risk of damage or destruction from natural disasters, adverse environmental conditions, and infestation of insects, molds, or rodents.

3.7.3 The records filing system shall be described in writing along with the filing system to be used. The filing system shall include a method for verifying that records received are in agreement with the transmittal document accompanying the records and are legible. In addition, the filing system shall account for supplemental information and the disposal of superseded records. The records storage system shall govern access to and control of files, including accountability for records removed.

3.7.4 When records are stored on magnetic or optical media, provisions to maintain the capability to retrieve the information for the life of the record shall be made. Compatible processing systems shall be available, or the information transferred to other media.

3.7.5 Retained records attached in binders or in folders or envelopes should be stored in steel file cabinets or on shelving in containers. Special processed records such as radiographs, photographs, negatives, microform, and magnetic media, shall be stored in a manner to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

3.7.6 Dual storage shall be provided for lifetime records, and, at a minimum, shall be at locations sufficiently removed from each other to eliminate the risk of exposure to a simultaneous hazard. This may be accomplished by backing up computer files on a routine basis to the MACTEC, Inc. corporate server or a client's server.

3.7.7 Local offices shall establish a process for temporary removal of records from their storage facility. At a minimum, a card system shall be implemented identifying the record(s) taken from the files by name, date, organization, and the temporary location of the record(s).

3.7.8 Local offices shall establish a process for storing records at a job site until the job is completed and the records are transferred to the local office or client for maintenance and storage.

3.7.9 Client records, whether held or generated by MACTEC, Inc., shall be transferred to the client in accordance with contractual requirements. At a minimum, an inventory of the records shall be made prior to a transfer of records. The client should acknowledge the records transfer by issuing MACTEC, Inc. personnel a signed receipt that is then placed in the project's files.

3.7.10 Records accumulated at various locations, prior to transfer, shall be accessible to the owner directly or through the procuring organization. The QA Coordinator, or designee, shall inventory the submittals, acknowledge receipt, and process these records. Final disposition of the records typically meets applicable regulatory and/or contractual requirements.

A supplier's nonpermanent records shall not be disposed of until the following conditions are satisfied:

A. Regulatory requirements are satisfied.
B. Operational status is achieved.
C. Warranty consideration is satisfied.
D. Purchaser's requirements are satisfied.

These requirements can be met by inclusion in the contractual documents or by the supplier providing MACTEC, Inc. with the documents.

4.0 RECORDS SCHEDULES

4.1. Each local office should establish a records disposition and retention schedule (see Appendix 17.1.1 for a typical example or NQA 1997 Non-Mandatory Guidance 17-1) that reflects the types of quality records generated by typical projects. When necessary, the corporate Quality Manager can provide guidance to the local offices' Quality Coordinators regarding records disposition and retention schedules.

4.2 Project Managers and/or Quality Coordinators shall specify the disposition schedule of project-specific records as part a project's Quality Project Plan.

APPENDIX

17.1.1 Typical Example of Records Disposition and Retention Schedule

- *See Policy Volume 17.0, Quality Assurance Records*

Appendix 17.1.1
Typical Example of Records Disposition and Retention Schedule

NOTE: THIS APPENDIX IS A TYPICAL EXAMPLE OF A RECORDS DISPOSITION AND RETENTION SCHEDULE AND SHOULD NOT BE CONSIDERED MANDATORY. THE INTENT IS TO PROVIDE AN EXAMPLE FOR QUALITY PROJECT PLANS THAT MAY REQUIRE A RECORDS DISPOSITION AND RETENTION SCHEDULE.

Records	*Description*	*Disposition*	*Retention Time*
Administration: Policies and Procedures	Records documenting company-approved methods or processes for performing activities to ensure uniformity, quality, and compliance with company, legal, and contractual requirements. Includes office and job practices, administrative handbooks, procedures manuals, and records retention requirements.	Active until policy/procedure is cancelled or superceded	Active + 5 years
Administration: Policies and Procedures Compliance	Records related to compliance with corporate policies and procedures. Includes records destruction certificates		Active + 5 years
Administration: Policies and Procedures Internal Audits	Records demonstrating compliance with internal policies and procedures. Includes audit reports, remedial activities (CAR's and Audit Report Findings). These audits are not required by government agencies or by statues or regulations.		Active + 5 years
Administration: Department Policies and Procedures	Records documenting departmental methods or processes for performing activities to insure uniformity and efficiencies	Active until policy/procedure is cancelled or superceded	Active + 1 year
Environment, Health, and Safety: General	Records related to environment, health, and safety not covered elsewhere, including chemical and analytical laboratory results; correspondence that does not fit into more specific retention groups; administrative records; environmental reports and assessments of a general nature for internal use and that are not required by law or regulation		3 years

Records	*Description*	*Disposition*	*Retention Time*
Environment, Health, and Safety: Air Quality	Records and information related to the monitoring, sampling, and analysis of air quality. Includes continuous emission monitoring (CEM) records; permit application; radon emissions monitoring; and the following as they relate to air quality: sewage treatment, waste disposal, wastewater, asbestos	Active until the life of the asset ceases that produces the emissions or until records transferred to client	Life of asset + 5 years
Environment, Health, and Safety: Water Quality	Records and information related to monitoring, sampling, and analysis of water quality (drinking water, well water, etc.). Includes permits, conformance and nonconformance records, bacteriological call analyses, chemical analyses, and system surveys	Active until transferred to client	Active + 10 years
Environment, Health, and Safety: Toxic/Hazardous Substance Control	Records documenting and tracking toxic substances (including asbestos, PCB's, chemicals, pesticides, radiation machines, etc.); any adverse reactions and risk notifications	Active until transferred to client	Active + 5 years
Environment, Health, and Safety: Solid Waste Management/ Disposal	Records related to management and disposal of solid waste. Includes waste inventories, waste management, and transportation records and manifests.	Active until transferred to client	Active + 5 years
Environment, Health, and Safety: Hazardous Waste/Storage & Disposal Facilities (RCRA Part A related)	Records related to hazardous waste disposal, environmental aspects of real estate purchases or sales, and hazardous materials/waste treatment, storage and disposal (TS&D) facilities (including underground storage tanks	Indefinite-records are reviewed periodically for changes in regulatory requirements, business needs, etc., to determine if any records can be safely destroyed, OR transfer to client	Indefinite
Environment, Health, and Safety: Internal Audits/Reviews	Records related to internal review, audit, investigation of company practices for compliance with environmental and safety laws and regulations; these reviews or audits are not required by government agencies or by regulations; includes conformance evaluations and follow-up actions	Active until completion of follow-up action or transferred to client	Active + 10 years

Records	*Description*	*Disposition*	*Retention Time*
Environment, Health, and Safety: Chemical Lab Analyses Master Records	Chemical laboratory analyses records that are a master record of the activities of the generating laboratories.	Active until transferred to client	Active + 10 years
Environment, Health, and Safety: Lab Notebooks	Records of environmental-related activities and findings of chemical lab analyses	Indefinite-records are reviewed periodically for changes in regulatory requirements, business needs, etc., to determine if any records can be safely destroyed, OR transfer to client	Indefinite
Environment, Health, and Safety: Employee Hazardous Exposure	Medical records related to cases of exposure, or possible exposure, to hazardous or toxic substances encountered by individual employees in the scope of employment. Includes monitoring records of employees where exposure may exist.	Active until employee termination	Active + 40 years
Environment, Health, and Safety: Workplace Monitoring/Material Safety Data Sheets (MSDS)	Records/information related to sampling of air and other contaminants in workplace areas, excluding individual employee monitoring date. Includes MSDS; industrial hygiene lab samples; the measurement, testing, and analysis of noise in the work environment.	Indefinite-records are reviewed periodically for changes in regulatory requirements, business needs, etc., to determine if any records can be safely destroyed, OR transfer to client. In general, workplace monitoring records and MSDS should be retained for 30 years after the last possible exposure by an employee to a facility's environment or to a specific chemical	Indefinite
Environment, Health, and Safety: Safety and Environmental Training	Records/information related to the content and administration of employee safety and environmental training for compliance with OHSA standards on heavy equipment, respirators, hazard communications, hazardous materials training, hearing conservation, and driver training	Active until termination of course or program or when the training is no longer required as a matter of law, or when transferred to client	Active + 30 years

Records	*Description*	*Disposition*	*Retention Time*
Environment, Health, and Safety: Equipment Safety	Records related to the testing, inspection and safe operation of equipment in the workplace	Active until the record is superseded or with disposition of the equipment or transferred to the client. Routine maintenance records may be destroyed 1 year after maintenance or overhaul	Life of equipment + 1 year
Purchasing: Supplier Reference Information	Records/information related to the availability of products and services from outside sources, including supplier quality records	Active until information is no longer current or relevant, or when it is superseded by updated, more current information, or transferred to the client	Active until superceded or no longer needed or transferred
General and Common: Periodic Replacement Records	Various reports, lists, indexes, and other records that are replaced periodically by updated records, such as indexes, manuals (property, materials, equipment, etc.)	Active until superseded	Active until superseded
General and Common: Project Administration	Records related to administration of projects, contracts, work orders that are not subject to any retention requirement specified in contractual requirements. Originals of the final work product and contracts are filed in an appropriate record index	Active until project completion or contract completion, when no longer needed, or when transferred to the client	Active while needed or until transferred
General and Common: References	Records and information maintained for reference purposes only. Includes general information and publications in the public domain, such as professional association proceedings, government regulations, etc.	Active until superceded or when no longer referenced or in use	Active while needed

Records	*Description*	*Disposition*	*Retention Time*
General and Common: Copies	Duplicates and convenience copies of records, including photocopy memoranda or reports, chronological or reading files that are copies of records maintained as backup by the originator, etc.	Retained as long as needed. If there is a business need to retain a duplicate record longer than one year, it may be retained for as long as needed, but NO LONGER THAN the retention requirement of the official record	Active while needed
General and Common: Non-records	Draft/working copies of final documents, and other items that are not an official record. Includes letters of transmittal that add nothing to the information transmitted; draft versions of documents that have been finalized	Active until superseded by more current items or when no longer referenced or in use	Active while needed
Training: General	Training, including quality training, based on project-specific requirements	Active until no longer needed or transferred to client	Active while needed or transferred
Training: Program Materials	Records/information related to the content of general training programs, including quality training for specific project requirements	Active until no longer needed or program ceases	Active while needed
Medical Records: Health and Safety	Medical records related to on-the-job accidents and illnesses	Active	Active + 40 years

Procedure Title: AUDITS

1.0 PURPOSE

This procedure defines how MACTEC, Inc. documents the methods and requirements for performing audits. MACTEC, Inc. uses a comprehensive system of planned and periodic audits to ensure the implementation and effectiveness of the overall QA Program. Audits are performed internally and for clients, as required.

2.0 SCOPE

2.1 The quality requirements contained in this section apply to MACTEC, Inc. and its subsidiaries when performing the following types of audits:

A. Internal Audits: Audits conducted to verify MACTEC, Inc.'s compliance to the QA Manual, procedures and contractual requirements.

B. Client Audits: Audits conducted by MACTEC, Inc. to verify compliance with client contractual and procedural requirements. Such audits are normally conducted to client procedures.

C. Client Supplier Audits: Audits conducted by MACTEC, Inc. personnel, when contracted by clients, to verify client's supplier's compliance with contractual and procedural requirements.

2.2 Internal audits are formal and typically scheduled with advance notification to the organization being audited.

3.0 GENERAL

3.1 PERFORMANCE OF AUDITS

3.1.1 Planned and scheduled audits are performed to verify compliance with all aspects of the QA Program, to verify effectiveness of QA program implementation, and to promote improvements. Audits are conducted in accordance with approved procedures and/or checklists to ensure thoroughness of the review. Checklists may be standardized, or they may be prepared for specific audits. Audit results are documented and reported to and reviewed by responsible management. Follow-up action is taken where indicated. The group performing audits has sufficient authority and freedom from the line to carry out its responsibilities.

3.1.2 Audits begin as early in the life of the activity as practical and are continued at intervals consistent with the schedule for accomplishing the activity.

3.1.3 Elements selected for audit are evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine their effective implementation.

3.1.4 Qualified personnel who do not have direct responsibility in the area being audited perform audits. Audits are performed under the direction of an auditor who meets the requirements of Section 2-2 in this manual. Audits shall be performed under the direction of a Lead Auditor for contracts that require the implementation of NQA-1and for non NQA-1 audits that require more than one auditor. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved with selection of the audit team.

3.1.5 Prior to an audit, a Lead Auditor, or other appropriate audit personnel, apprise responsible management of the activity being audited and the scope of the audit.

3.1.6 Objective evidence of quality-related practices, procedures and instructions, effectiveness of implementation, and the conformance with policy directives are evaluated. Audits include evaluation of work areas, activities, processes, services and items, interviews, and the review of documents and records, as applicable.

3.1.7 Auditing personnel document their audits; and the management of the area being audited reviews the audit results. Deficiencies identified by the audit team or individuals are documented on an Corrective Action Request (see Appendix 16.1.1, Section 16-1) and discussed with the responsible management of the audited function. The responsible management will receive a formal notification of the audit results. Conditions requiring prompt corrective action are reported immediately to management of the audited organization.

3.1.8 Internal or external QA audits, or both, are scheduled in a manner that provides coverage and coordination with ongoing QA program activities. Audits are scheduled on the basis of the status and importance of the activities. Audits may be conducted without advance notice, should circumstances warrant. The audit schedule should be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits are supplemented by additional audits of specific subjects when it is necessary to provide adequate coverage.

3.1.9 Audits conducted under the MACTEC, Inc. program are performed on a continuing basis such that applicable elements are addressed at intervals not exceeding two years. Audits are formal and scheduled with advance notification to the organization being audited. Audits are formally documented in an audit report signed by the audit Team Leader. The report carries a unique identification (e.g., report number, title, and date; a clear statement of the audit scope; a summary of audit results including auditors' names;

personnel contacted; specific requirement sources; procedural sections; activities audited; documents reviewed; findings, observations or concerns; description of each reported adverse audit funding in sufficient detail to enable corrective action to be taken by the audited organization; plan for the follow-up; and any necessary attachments. The audit plan or checklist used is not a part of the report but should be maintained for reference as a part of the permanent audit file.

3.1.9 Audit follow-up measures include contact with responsible management of the audited organization to resolve deficiencies and ensure timely response to the Audit Finding Report and keeping abreast of the progress of the corrective action. Response should be provided within 30 days of receipt.

The QA Coordinator, or his designee, is responsible for cognizant office and project audits. This does not preclude the appointment of a technical and/or administrative representative to participate directly in the audit or to serve as a consultant. The responsibilities of the QA Coordinator, or his designee, include, as a minimum, the following:

A. Scheduling, coordinating and reporting MACTEC, Inc. audits.

B. Establishing an audit schedule.

C. Generating audit checklists and/or procedures that define the requirements to be audited, as required.

D. Conducting and/or coordinating the performance of audits as planned.

E. Issuing audit reports, as required.

F. Initiating Corrective Action Requests, as required, for a significant finding.

G. Conducting follow-up audits to determine the implementation and effectiveness of corrective action(s).

H. Distributing copies of the audit schedule reflecting accomplishment of such audits and results summaries to the corporate QA Manager and affected organization managers for information and evaluation.

3.2 PREPARATION

3.2.1 Audit Plan

The auditing organization develops and documents an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited,

organizations to be notified, applicable documents, schedule, and written procedures or checklists.

3.2.2 Selection of Audit Team

An audit team is identified prior to the beginning of each audit. This team includes one or more auditors.

For NQA-1 audits and for non NQA-1 audits conducted by more than one person, an Audit Team Leader shall be selected; this individual organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The Audit Team Leader also ensures that the audit team is prepared prior to initiation of the audit.

NOTE: For NQA-1 audits, the Lead Auditor shall meet the requirements of Section 2-2, Paragraph 4.3.1, of this manual.

For non NQA-1 audits, the Lead Auditor shall meet the requirements of Section 2-2, Paragraph 4.3.8, of this manual.

3.3 RESPONSE

3.3.1 Management of the audited organization or activity must investigate adverse audit findings; schedule corrective action, including measures to prevent recurrence; and notify the appropriate organization in writing of action taken or planned.

3.3.2 The adequacy of audit responses is evaluated by or for the auditing organization.

3.4 FOLLOW-UP ACTION

3.4.1 Follow-up action is taken to verify that corrective action is accomplished as scheduled.

3.5 TYPES OF RECORDS

3.5.1 Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.

3.6 QUALIFICATION OF AUDITORS

3.6.1 Auditors are trained as necessary and qualified in accordance with Section 2-2 of this manual. The QA Coordinator, or his designee, is responsible for the assignment of the Auditor/Audit Team Leader and team members, where applicable, who are qualified to perform each assigned task.

3.7 MACTEC SERVICES PROVIDED FOR CLIENT PROGRAMS

3.7.1 MACTEC, Inc. audits of or for a client shall be performed by audit teams (which may have only one team member) of which the Audit Team Leader is a qualified Lead Auditor in accordance with Section 2-2 of this manual. Audit preparation, conduct, and reporting

is accomplished in accordance with the applicable client QA program requirements or, if requested by the client, in accordance with MACTEC, Inc. audit practice and this section of the QA Manual.

3.7.2 Audit plans developed or modified for client's use are processed in accordance with client programs as applicable.

4.0 RECORDS

At a minimum, the quality records generated by this section include the audit reports. These reports are maintained and stored in accordance with Section 17-1 of this manual.

APPENDIX

18.1.1 Typical Audit Finding Report

- *See Policy Volume 18.0, Audits*

CHECKLIST FOR REVIEWING EPA QUALITY MANAGEMENT PLANS

CHECKLIST FOR REVIEWING EPA QUALITY MANAGEMENT PLANS

This checklist will be used to review the Quality Management Plans (QMPs) that are submitted to the Quality Staff of the Office of Environmental Information (OEI) for Agency review under EPA Order 5360.1 A2. Items from this checklist are discussed in detail in Chapter 3 of EPA Manual 5360 A1 and in *EPA Requirements for Quality Management Plans (QA/R-2)*. Consult these resources for more information on the items below.

Note that all items below must be included in a QMP. If an item is not relevant, an explanation must be provided. Also note that process may either be described or referenced in the QMP; however, all references should be readily accessible within the organization and provided to the Quality Staff with the QMP.

	Page(s)	Comments
MANAGEMENT AND ORGANIZATION		
1. Signed and dated by senior manager?	Cover	
2. Signed and dated by senior line management?		Signoff Sheet w/ CASTNet Proj. Mgr. Sig.
3. Signed and dated QA manager?	Cover	
4. Includes signature lines for Quality Staff approval?	NA	
5. Includes signature lines for OEI approval?	NA	
6. Includes statement of the organization's QA policy?	1-8	Policy Vol
6a. QA policy statement includes general objectives/goals?	1-8	"
6b. QA policy statement includes allocation of intramural, extramural, and travel funds and personnel?	Proc. Vol 2-3, p.1-3	

	Page(s)	Comments
7. Includes organizational chart?	2	Policy Vol.
7a. Organizational chart identifies all components of organization?	1-2	
7b. Organizational Chart identifies position of QA manager?		
7c. Organizational Chart identifies lines of reporting of the QA manager?		
7d. Organization Chart identifies any other QA staff?		
8. Includes discussion of authorities of the QA manager and staff?	3-7	Procedure Vol. Section 1-1
9. Documents the independence of QA manager?	3-7	
10. Describes procedures to ensure QA staff have access to appropriate levels of management?	2-7	
11. Discusses technical activities or programs that require quality management?	1-4	Proc. Vol. sect. 2-1
12. Discusses where oversight of delegated or extramural programs is needed?	5, 10 2-3 * Also see	Proc. Vol. Sec. 2-2 " " 10-1 CASTNet QMP Sec. C.1.1

	Page(s)	Comments
13. Identifies where internal coordination of QA and QC activities among organizations is needed?	2 – 3 1 – 4 *CA/NA	Proc Vol. Sec. 2-1 " " " 4-1 Not QMP Sec. C.1
14. Discusses how management assures understanding and implementation in all programs?	2 - 5 1 - 4 * CA/NA	Proc. Vol. Sec. 2 - 1 " " 4 - 1 Not QMP Sec C.1
15. Describes process for resolving disputes?	NA* *However-	Proc. Vol. Sec 1-1 p. 6
QUALITY SYSTEM COMPONENTS		
16. Includes description of quality system?	1 – 8	Policy Vol.
17. Describes principal quality system components (e.g., quality system documentation, annual reviews and planning, project-specific quality documentation? (Note, identify components in Column 3.)	2-3,7 1 – 3 1 - 11	Proc. Vol Sec 2-1 Proc. Vol Sec 2-3 " " 17 - 1
18. Description of components includes how they are implemented?	2 -4 3 -4 1 - 11	" " 2 - 1 " " 2 -4 " " 17 - 1
19. Description of components includes responsibilities of management and staff?	3 - 7	" " 1 - 1
20. Lists tools for implementing each component (e.g., QMPs, Quality Systems Audits, Training Plans, QA Project Plans? (Note: list tools in Column 3.)	1 - 7 1 - 21	2 - 1 2 - 2 Forms & Procedures are discussed throughout the Proc. Manual. Policy Volume references the 18 procedures available.

	Page(s)	Comments
21. Identifies internal organizations that develop QMPs?	4 Attn Sec. 2-1 pp. 1-5	Proc. Vol. 1-1; Pw policy volume, offices develop QPPs. The QMP provides the corporate QMP.
22. Identifies review and approval procedures for these internal QMPs?	1-3 1-4	Proc. Vol. 2-3 " 2-4
23. Includes assurance that QA responsibility is incorporated into performance standards (consistent with Agency personnel policy)?	NA	
QUALIFICATIONS AND TRAINING		
24. States policy regarding QA training for management and staff?	4-5	Proc. Vol. 2-1
25. Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related qualifications?		
26. Describes process for ensuring personnel maintain quality-related qualifications?		
27. Describes process for identifying the need for quality-related retraining based on changing requirements?		
28. Includes roles, responsibilities, and authorities in description of above processes?	3-7	Proc. Vol. sec. 1-1

	Page(s)	Comments
PROCUREMENT OF ITEMS AND SERVICES		
29. Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts)?	1-4	Proc. Vol Sec 4-1
29a. Review process ensures documents are complete and accurate?		
29b. Review process ensures agreement clearly describes the item or service needed?		
29c. Review process ensures agreement describes the associated technical and quality requirements?		
29d. Review process ensures agreement describes the quality system elements for which the supplier is responsible?		
29e. Review process ensures that the supplier's conformance to the customer's requirements will be verified?		
30. Describes process for reviewing and approving applicable responses to solicitations to ensure that they satisfy all technical and quality requirements?	5-9	Proc Vol. 7-1
30a. Review process ensures the review of evidence of the supplier's capability to satisfy EPA quality requirements?	NA	
30b. Review process ensures procured items and services are acceptable?	1-4 1-9	Proc. Vol. 4-1 " 7-1
31. Describes process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?	NA*	*However, see 30b.

	Page(s)	Comments
32. Includes discussion of any policy and criteria for delegations of review of QA Project Plans and QMPs?	NA	
33. Describes process to ensure EPA extramural agreement policies satisfied?	↓	
34. Includes roles, responsibilities, and authorities in description of above processes?	3-7 1-4 1-9	Proc. Vol. 1-1 ↓ 4-1 7-1
DOCUMENTS AND RECORDS	~~3~~ NI	
35. Describes process for identifying quality-related documents and records (including electronic) requiring control?	3	Proc. Vol. 17-1
36. Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?	1 - 11	
37. Describes process for ensuring that records and documents accurately reflect completed work?	1-6	
38. Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?	1 - 11	
39. Describes process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?	1-6	

	Page(s)	Comments
40. Above processes comply with EPA Order 2160 and EPA Directive 2100, Chapter 10?	NA	
41. Includes roles, responsibilities, and authorities in description of above processes?	1-2	Proc. Vol. 17-1
COMPUTER HARDWARE AND SOFTWARE		
42. Describes process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software?	4-5	Proc. Vol. 3-1
43. Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?	~~1-9~~ 7-11	~~7-11~~ See appendices to QMP.
44. Describes process for evaluating purchased hardware and software?	1-9	Proc. Vol. 7-1 * CANTest QAPPs, B2.3 & B7.5
45. Describes process for ensuring that data and information produced from or collected by computers meet applicable requirements and standards?		
46. Includes roles, responsibilities, and authorities in description of above processes?		+ CANTest QAPP sec. A.4
47. Are the requirements of EPA Directive 2100 are addressed in the above processes?		Assumed EPA internal.

	Page(s)	Comments
PLANNING		
48. Includes a description of the systematic planning process for environmental data operations?	1-3	Proc. Vol. 2-3
48a. Does process include identification and involvement of all customers and suppliers?		
48b. Does process include description of the project goal, objectives, and questions and issues to be addressed?	1-4	Proc Vol. 2-4 * CA/TNCI QAPP A.5-A.6
48c. Does process include identification of project schedule, resources, milestones, and any applicable requirements?		
48d. Does process include identification of the type and quantity of data needed and how the data will be used to support the project's objectives?		** CA/TNCI QAPP A.5-A.7
48e. Does process include specification of performance criteria for measuring quality?		
48f. Does process include specification of needed QA and QC activities to assess the quality performance criteria?		
48g. Does process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?		
48h. Does process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?		

	Page(s)	Comments
49. Describes process for developing, reviewing, approving, implementing, and revising QA Project Plans?	1-4	Proc. Vol. 2-4
50. Describes process for evaluating and qualifying data collected for other purposes or from other sources?	3 (Non-D. not measurement)	- Also CASWRAP QAPP sec. B.7.4, B.2.1, B.2.3.1
51. Includes roles, responsibilities, and authorities in description of above processes?	3-7	Proc. Vol. 1-1 + CASWRAP QAPP/sec. A.4
IMPLEMENTATION OF WORK PROCESSES		
52. Describes process for ensuring that work is performed according to planning and technical documents?	~~2~~ 1-3 1-8 1-5	Proc. Vol. 2-3 " 3-1 " 18-1 + QAPP sec. C
53. Describes process for identifying operations needing procedures?		
54. Describes process for preparation, review, approval, revision, and withdrawal of these procedures?		+ QAPP sec. A.9
55. Describes policy for use of these procedures?		+ Throughout QAPP (highlight sec. A)
56. Describes process for controlling and documenting the release, change, and use of planned procedures?	*	+ QAPP sec. A.9 Proc. Vol. 17-1 pp. 1-11 also.

	Page(s)	Comments
56a. Process includes description of necessary approvals?	1-7 1-3 1-4	Proc. Vol. 1-1 ↓ 2-3 2-4
56b. Process includes removal of obsolete documentation from work areas?	1-3	Proc. Vol. 6-1
56c. Process includes verification that the changes are made as prescribed?		
57. Includes roles, responsibilities, and authorities in description of above process?		
ASSESSMENT AND RESPONSE		
58. Describes the process for assessing the adequacy of the quality system at least annually?	6-7	Proc. Vol. 2-1
59. Describes the process for planning, implementing and documenting assessments and reporting results to management?	1-21	Proc. Vol. 2-2 (Also @ Appx. C)
59a. Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?		
59b. Process includes determining the level of competence, experience and training needed for assessment personnel?	(1-9)	
59c. Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?	(7)	4.3.4

	Page(s)	Comments
59d. Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom?	1-7	Proc. Vol. 1-1
60. Describes process for management's review of, and response to, findings?	1-8 1-6	15-1 16-1
61. Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?	1-6	16-1
61a. Process includes ensuring corrective actions are made promptly?		
61b. Process includes confirming the implementation and effectiveness of any corrective action?	~~✓~~ N/I	
61c. Process includes documenting actions?	✓	
62. Describes process for addressing disputes encountered as a result of assessments?	6	1-1
63. Includes roles, responsibilities, and authorities in description of above processes?	1-6	16-1

	Page(s)	Comments
QUALITY IMPROVEMENT		
64. Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?	1-7	Proc. Vol. 2-1
65. Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?	1-7 1-7 1-8 1-6	Proc. Vol 1-1 2-1 15-1 16-1
66. Includes roles, responsibilities, and authorities in description of above processes?	↓ (11)	↓ (11)
OTHER REVIEW CRITERIA		
67. Are regulatory or other citations accurate?	7-8	Policy Vol.
68. Are there any inconsistencies in the text?	None observed	
69. Is the writing clear?	Yes	
70. Are organizational units identified consistent with the most recent reorganization?	Yes	
71. Are past QS management assessment findings resolved? (Put date of Final Report in Column 3.)	)	Program implementation is 3/02.

	Page(s)	Comments
72. Are activities described in the QMP consistent with QA Annual Report and Work Plans?	NA	see #71 comment.
73. Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization's QMP)?	?	Question unclear, but in general see Proc. Vol. 2-1 pp. 2-3

Appendix A

Retraining

Retraining

When job requirements change, the need for retraining to ensure continued satisfactory performance in achieving and maintaining data quality indicators (DQI) and data quality objectives (DQO) on EPA field measurement projects will be evaluated. Job requirements could change as the result of new or modified field instruments, new analytical chemistry instruments, new software, or new procedures. The need for retraining staff on EPA projects managed by MACTEC will be evaluated annually by project or line management. The retraining will be accomplished and documented according to the requirements of project specific QAPP.

The process identifying the need for quality-related retraining based on changing job requirements can best be explained by providing three examples from the Clean Air Status and Trends Network (CASTNet):

1. Each CASTNet site operates a wetness sensor whose data are used for input to a mathematical model that simulates atmospheric dry deposition. Early in the project the quality of the wetness data indicated the sensors were inadequate to provide the required model input. A different supplier was identified and replacement sensors were acquired. The new sensors also required new calibration equipment to reproduce a standard resistance. The wetness sensors were fitted with a port to receive the test standard. Field technicians were trained to install the test port and set the wetness sensor sensitivity using the standard resistance. The instrument replacement and subsequent training resulted in consistency in wetness sensor data among all sites.

2. During the first quarter of 2000, MACTEC procured two new ion chromotographs for use in the analytical chemistry lab in Gainesville, FL. Although these instruments were similar to others already in use in the lab, the dedicated software provided with the instruments required additional training. Instrument operators were trained in use of the new instruments and its software. This training has resulted in consistent operation of the instruments and the production of lab measurements that have met all CASTNet DQI.

3. CASTNet required the development of a relational, database management system to archive and analyze the wide variety of measurements. The data management system included a variety of software products to assist data analysts in validating the measurements. The analysts were trained to use the new database management system, which has resulted in the consistent production and delivery of data that meet DQI.

Appendix B

Review and Approval of Suppliers' Quality Related Documentation

Review and Approval of Suppliers' Quality Related Documentation

Project QA supervisors are responsible for the review and approval of quality-related documents that are produced by suppliers. MACTEC requires that supplier-produced QMP and QAPP include approval/signature lines for the MACTEC project manager and project QA supervisor. The QA supervisor has the authority to reject quality-related documentation. The QA supervisor will notify the project manager of any problems with quality-related documentation. The project manager will notify and discuss with supplier for corrective action. Inadequate quality-related documentation could cause the rejection of a supplier. A review of quality-related documentation is an inherent component of the procurement process.

Appendix C

Chain of Custody and Confidentiality Procedures

Chain of Custody and Confidentiality Procedures

MACTEC requires the preparation and implementation of chain of custody and confidentiality procedures on all EPA data collection projects. These procedures are documented in project specific QAPP. A proper sample custody system ensures that data quality is not compromised due to faulty or inadequate documentation, shipping errors, and/or contamination during sample transfer. Sample custody procedures are designed to create an accurate record that traces sample handling from sample preparation through computer storage of the data and to ensure the maintenance of sample integrity through traceability of the materials that contact the sample.

MACTEC considers all EPA data as confidential. MACTEC will not release EPA data without written permission from the agency. All EPA data are archived in a secure database. Data security is implemented using access control and data backup procedures, which are described in project specific QAPP.

Appendix D

Changing Requirements for Hardware and Software

Changing Requirements for Hardware and Software

Changes to hardware/software configurations, components, or project requirements are assessed to determine the impact of the change to quality objectives and job/user requirements. This process is described in project specific QAPP. Software upgrades or code changes are typically implemented to (1) improve performance, (2) increase capabilities, (3) correct bugs in earlier versions, or (4) for any combination of the above. Software and also hardware upgrades are tested using two general approaches:

1. For major upgrades test systems are established to operate both the old method (or hardware) and the new method in tandem for a period of time to ensure that the new method is performing the same function as the old system.

2. For a minor modification., the new software or hardware is evaluated using a test database to ensure the change works correctly and does not cause unanticipated problems. All software or hardware tests are documented and archived as part of project requirements.

Finally, new software or hardware is evaluated in order to assure the maintenance of DQI and DQO.

Appendix E

REVIEW AND APPROVAL OF THE QUALITY ASSURANCE MANUAL

REVIEW AND APPROVAL OF THE QUALITY ASSURANCE MANUAL

The corporate QA Manager, or designee, is responsible for the preparation, control and revision, and distribution of the QA Manual.

Each QA Manual section contains a revision number and the date of issuance and is approved and signed by the MACTEC, Inc. Chairman and CEO and corporate QA Manager.

The Corporate Development Office shall be responsible for distribution of QA Manuals and section revisions to locations when required. The QA Manual also is available electronically via the MACTEC, Inc. corporate website.

The regional and local Office Managers and QA Coordinators perform the review of original QA Manual sections. The corporate QA Manager will distribute (or provide access to) a review draft to the designated reviewers via electronic mail along with a request to review the manual and provide comments by a certain date. The process is repeated until the QA Manager and designated reviewers conclude the document satisfies internal and external requirements as stated in the manual. The final document is then submitted to the Chairman and CEO for approval. Once approved by the QA Manager and Chairman and CEO, the finalized document is posted on the MACTEC, Inc. corporate website accessible to all MACTEC, Inc. employees and physical copies are distributed as appropriate.

If a finalized QA Manual section should subsequently require revision, that section is reissued in its entirety with each page indicating the new revision number and is accompanied by a change in the Table of Contents. Revisions are reviewed and approved in the same manner as the original sections.